v.a.c.ulta™
KCI Healing by design

User Manual

Do not discard. Please retain this user manual for future reference. For additional copies, in the US, visit www.kci1.com, www.vaculta.com or contact KCI at 1-800-275-4524. Outside the US, visit www.kci-medical.com.

KCI®

Warning

Important Safety Information Accompanies This Device

Indications, Contraindications, Warnings, Precautions and other Safety Information are contained in the V.A.C.Ulta™ Therapy System Safety Information Sheet. This information sheet is included with the therapy unit and also included in V.A.C.Ulta™ Dressing cartons. Please consult the V.A.C.Ulta™ Therapy System User Manual and the Safety Information Sheet before applying V.A.C.® Therapy or V.A.C. VeraFlo™ Therapy. If there are questions, or if this information sheet is missing, immediately contact your local KCI representative.

Additional product information can be found at www.kci1.com (US), www.kci-medical.com (OUS) or www.vaculta.com.

As with all prescription medical devices, failure to follow product instructions or adjusting settings and performing therapy applications without the express direction and/or supervision of your trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury. For medical questions, please consult a physician. In case of medical emergency, immediately contact your local emergency services provider.

CAUTION: Federal law (US) restricts this device to sale or rental by or on the order of a physician.

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Important Information For Users

In order for KCI products to perform properly, KCI recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- Use this product only in accordance with this manual and applicable product labeling.
- Assembly, operations, extensions, re-adjustments, modifications, technical maintenance or repairs must be performed by qualified personnel authorized by KCI.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Use only V.A.C.® Dressings with this product.
- Keep this product away from heated surfaces.
- Although this product conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- Avoid spilling fluids on any part of this product.

  Fluids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards to patient and staff. If spills do occur, unplug the unit immediately and clean with an absorbent cloth. Ensure there is no moisture in or near the power connection and power supply components before reconnecting power. If the product does not work properly, contact KCI.

- Do not use this product while bathing / showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Disconnect the unit from dressing and contact KCI.

Notice

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the product information label for specific voltage.

Introduction

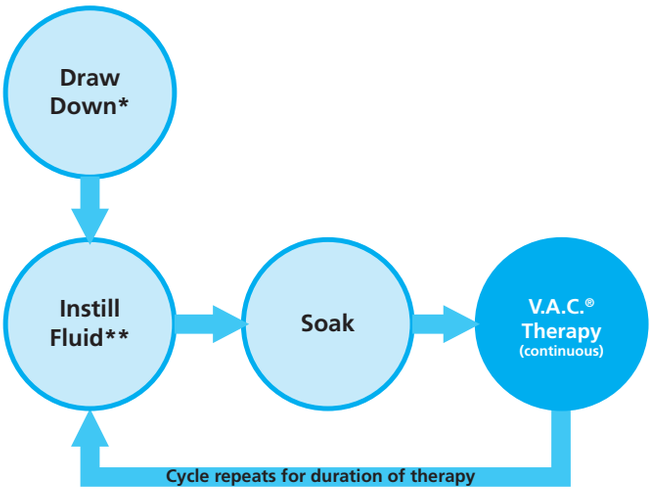
The V.A.C.Ulta™ Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy (**2**) with an Instillation Therapy (V.A.C. VeraFlo™ Therapy (**1**) option. Negative Pressure Wound Therapy is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Instillation Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C.Ulta™ Negative Pressure Wound Therapy System is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

The V.A.C.Ulta™ Negative Pressure Wound Therapy System provides for a variety of therapeutic options that allow for wound healing customization and a flexible approach to wound care.

V.A.C. VeraFlo™ Therapy:

1 **Phases of V.A.C. VeraFlo™ Therapy**
(Start Phase: Instill)

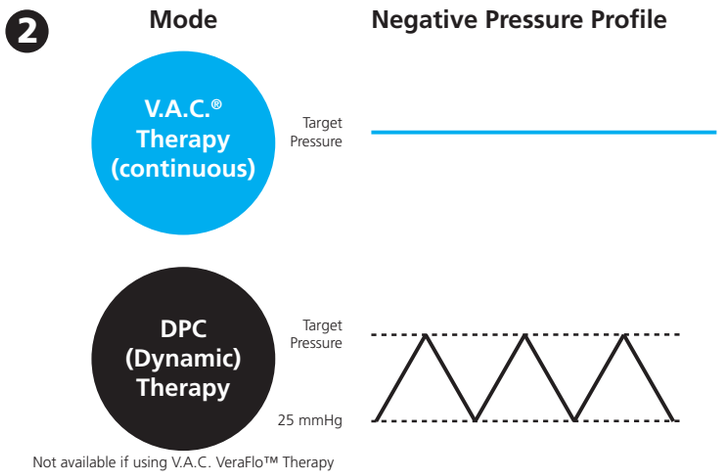


* Seal Check™ Leak Detector

** Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VeraFlo™ Therapy.

OR

V.A.C.® Therapy (with two negative pressure modes):



All of the V.A.C.® Therapy Dressings are available for use with the V.A.C.Ulta™ Therapy Unit. Additional dressings specific to V.A.C. VeraFlo™ Therapy are also available.

The V.A.C.Ulta™ Negative Pressure Wound Therapy System is intended to be operated by qualified clinical caregivers in the acute care setting. In-service and training programs for use of V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy are available. Therapy unit information signals should be monitored by the clinical caregiver. Patients are not expected to apply or change V.A.C.® Dressings or adjust therapy unit settings.

V.A.C.Ulta™ Therapy System Key Features

The V.A.C.Ulta™ Therapy Unit incorporates all the valued features from previous generation KCI negative pressure therapy devices with new, more advanced features.

New Features

Large Interface Screen: Intuitive, easy to use menu for simplified therapy programming. Unit can be programmed for V.A.C.® Therapy or V.A.C. VeraFlo™ Therapy.

Volumetric Delivery: V.A.C.Ulta™ Therapy Unit provides volumetric fluid delivery utilizing a pump for reliable fluid delivery.

(DPC) Dynamic Pressure Control™ Therapy: Dynamic Pressure Control™ Therapy is the evolution of the intermittent therapy in the previous generations of V.A.C.® devices. It maintains a low level of negative pressure at the wound site between cycles. It helps prevent leaks and fluid accumulation that can occur when there is no negative pressure at the wound site. It is also designed to prevent patient discomfort from foam expansion and compression between cycles. DPC is available for use in V.A.C.® Therapy mode, but not if V.A.C. VeraFlo™ Therapy is selected.

Dressing Soak: This tool allows the user to soak the dressing in the wound with instillation solution in preparation for a dressing change to facilitate dressing removal, potentially improving patient comfort.

Test Cycle: This tool is used to perform an abbreviated V.A.C. VeraFlo™ Therapy instillation cycle. Each phase of the cycle will be tested to ensure system is set up and functioning as intended.

Fill Assist: Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent

instill phase of V.A.C. VeraFlo™ Therapy.

V.A.C. VeraLink™ Cassette: This new disposable component connects the V.A.C.Ulta™ Therapy Unit to the solution bag / bottle and dressing tubing. It provides convenient solution storage and delivery.

Retained Features

Touch Screen User Interface: The touch screen user interface allows for easy navigation through operational and help menus. A screen guard is available to help prevent unintentional changes. A settings lock is available to prevent patient access to therapy settings.

Adjustable Negative Pressure Settings and Therapy Modes: Settings can be selected from a range of 25 mmHg to 200 mmHg in increments of 25 mmHg. In addition, the V.A.C.® Therapy mode can be set for continuous negative pressure or Dynamic Pressure Control™ Therapy.

Seal Check ™ Leak Detector: This tool assists the user in finding negative pressure leaks in the system through the use of audible tones and on-screen visual aids during the troubleshooting process.

History Reports: The V.A.C.Ulta™ Therapy System provides three possible reports: 1. Alarm History, 2. Therapy History, and 3. Patient History. These chronologically logged reports include the date and times for therapy starts / stops, therapy settings, alarm occurrences, and disposable component changes. They can be reviewed on-screen or transferred electronically from the V.A.C.Ulta™ Therapy Unit via a non-powered USB flash memory stick or SD memory card.

SensaT.R.A.C.® System: The SensaT.R.A.C.® System (also incorporated in the V.A.C. VeraT.R.A.C.™ Pad and V.A.C. VeraT.R.A.C. Duo™ Tube Set) monitors and maintains target pressure at the wound site, helping to deliver consistent therapy. This system includes therapy unit hardware and software, wound exudate collection canister, canister detection method, multi-lumen tubing, connector and SensaT.R.A.C.® Pad.

In-Line Tubing Connectors: The system incorporates an in-line dressing connector and tubing clamps to conveniently allow the wound dressing to be temporarily disconnected from the therapy unit.

Canisters: The V.A.C.Ulta™ Therapy Unit is optimized for use with 500 mL or 1000 mL canisters. These are the same canisters used with InfoV.A.C.® Therapy Unit. Canisters are single use, latex free, sterile components.

Canister Release Button: The canister release button is illuminated and will flash when the canister is full.

Intensity Setting: Intensity is related to the time it takes to reach the target negative pressure therapy level after the initiation of therapy. The lower the intensity setting, the longer it will take to reach the target negative pressure.

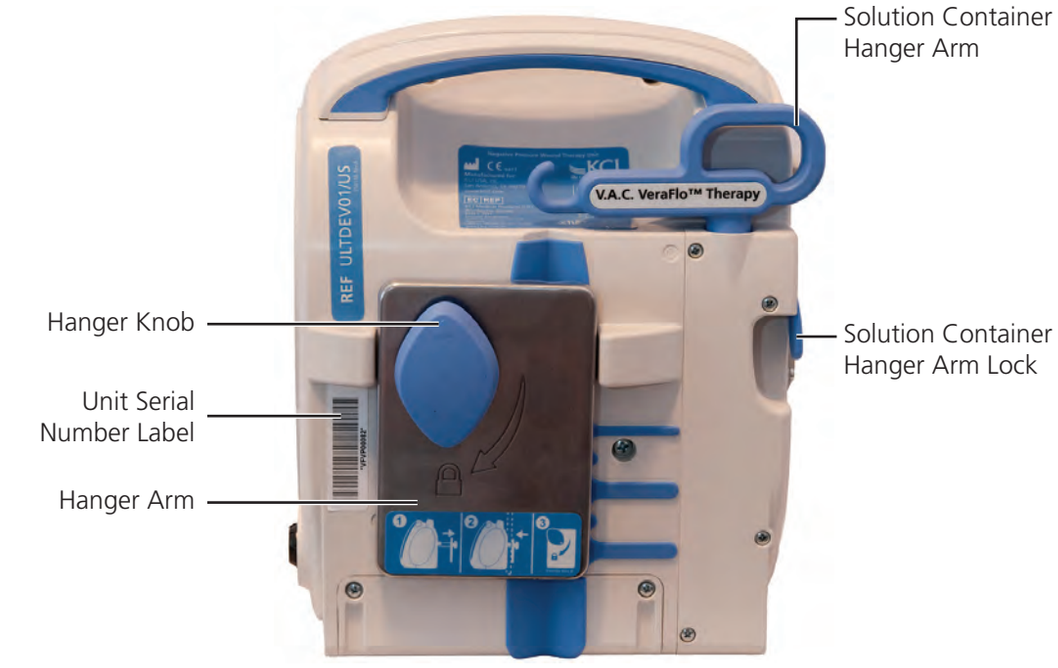
Wound Image Analysis: Digital wound images can be uploaded from a digital camera into the V.A.C.Ulta™ Therapy Unit. When the wound perimeter is traced on-screen with the provided stylus, wound image surface area and volume can be calculated and trended by the therapy unit. A chronological graphical history of the wound (with wound image area trend chart) can be viewed on-screen or this information can be transferred from the V.A.C.Ulta™ Therapy Unit electronically. This information is intended to be used by the treating clinician as a mechanism for providing a record of wound healing progress; it is not intended for use in the diagnosis and treatment of wounds.

Hanger Mechanism: The therapy unit can be securely mounted to an I.V. pole, a bed footboard or a wheelchair.

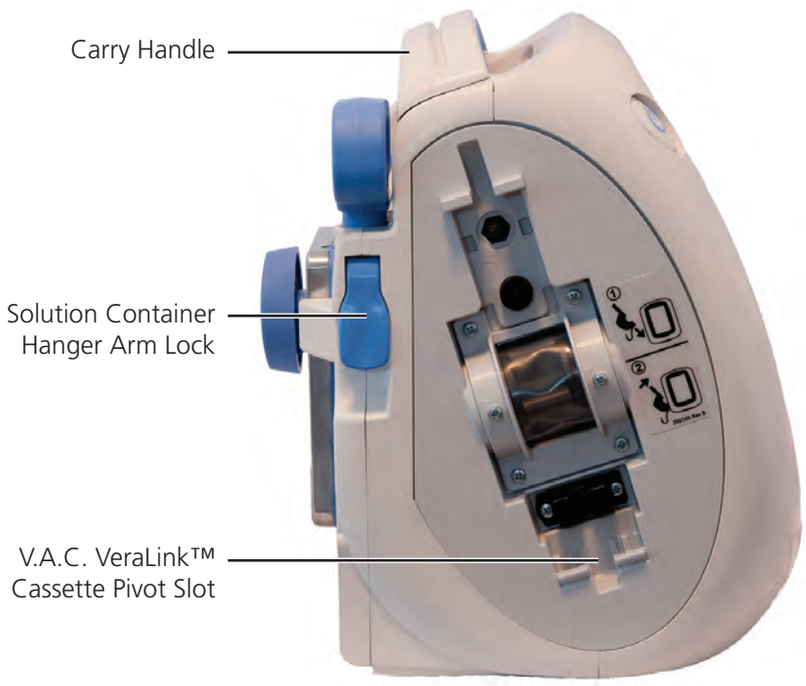
Battery Operation: In order to facilitate patient transfer, battery operation is available with the V.A.C.Ulta™ Therapy Unit. During typical usage, the battery may provide up to six hours of operation before needing to be recharged.

V.A.C.Ulta™ Therapy Unit Feature Identification

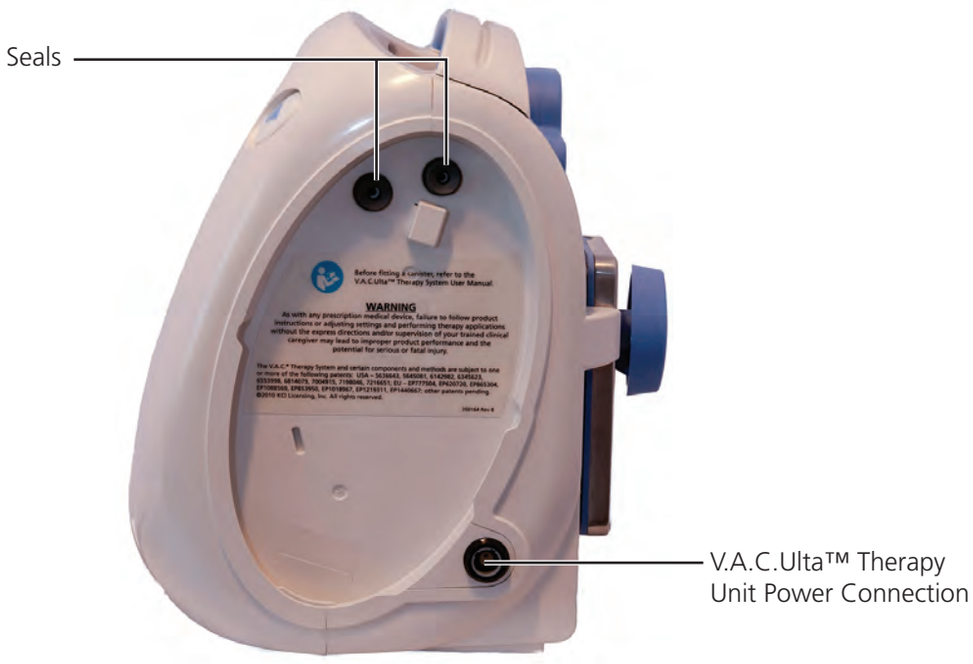
V.A.C.Ulta™ Therapy Unit - Front



V.A.C.Ulta™ Therapy Unit - Back



V.A.C.Ulta™ Therapy Unit - Left



V.A.C.Ulta™ Therapy Unit - Right

Charge Battery

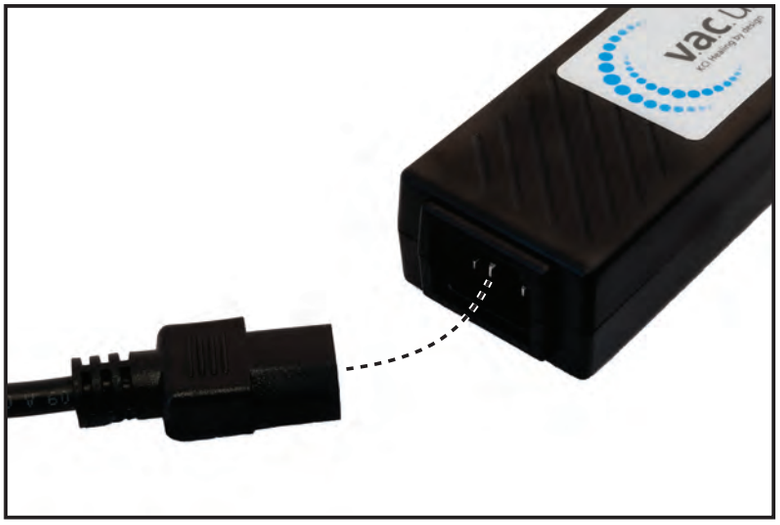
The V.A.C.Ulta™ Therapy Unit comes with its own power supply and a rechargeable battery. The battery is not user accessible or serviceable. The power supply has a two-part cord, one that plugs into an AC wall outlet and one that plugs into the V.A.C.Ulta™ Therapy Unit.

Use only the power supply provided with the V.A.C.Ulta™ Therapy Unit. Using any other power supply may damage the V.A.C.Ulta™ Therapy Unit.

If environmental conditions (specifically, low humidity) pose a risk of static electricity, take care when handling the V.A.C.Ulta™ Therapy Unit while it is out of the carrying case and plugged into an AC wall outlet. In rare instances, discharge of static electricity when in contact with the therapy unit may cause the touch screen to darken, or the therapy unit to reset or turn off. If therapy does not restart by powering the unit off and then on, immediately contact KCI.

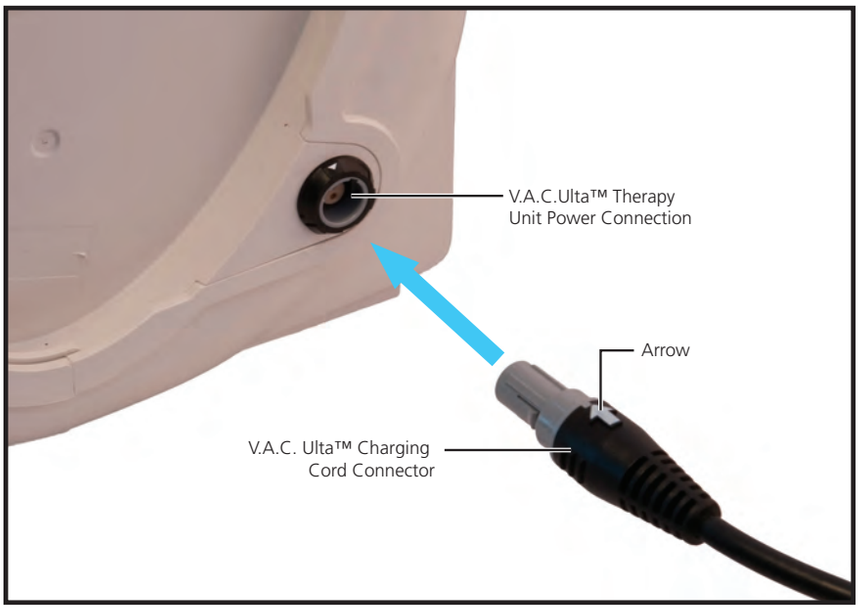
Power cords may present a tripping hazard. Ensure that all cords are out of areas where people may walk.

1. Plug the AC power cord into the DC power supply.

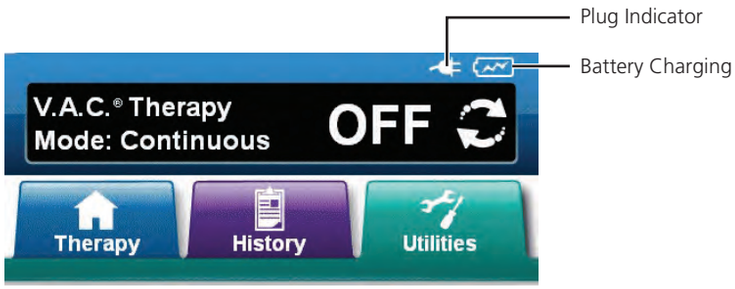


2. Plug the AC wall plug into an AC wall outlet.

3. Locate the arrow on the charging cord connector. The arrow should face up as the connector is plugged into the power connection on the V.A.C.Ulta™ Therapy Unit.



4. A plug indicator appears on screen while the unit is plugged into a wall outlet.



It should take approximately six hours to fully recharge the battery. To maximize battery life, keep the unit plugged in whenever possible.

When the V.A.C.Ulta™ Therapy Unit is correctly plugged into the V.A.C.Ulta™ Power Supply, the battery charging indicator light on the front of the unit (pg. 14) will glow amber while the battery is charging. When the battery has reached full charge the battery charging indicator light will glow green.

Therapy Unit Placement

The V.A.C.Ulta™ Therapy Unit can be attached to an I.V. pole or the footboard of a hospital bed. If required, it can be placed on a solid, level surface where it does not cause an obstruction. The V.A.C.Ulta™ Therapy Unit should be placed where cables and tubes cannot be caught on passing objects.

Power cords and tubing may present a tripping hazard. Ensure that all cords and tubing are out of areas where people may walk.

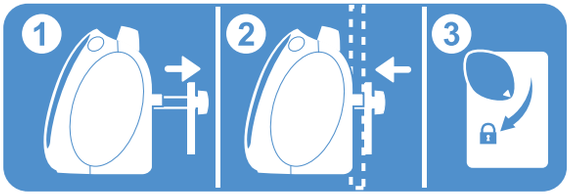
The V.A.C.Ulta™ Therapy Unit is not to be carried or worn by an ambulatory patient. Consult your physician and contact KCI for V.A.C.® Therapy Units designed for ambulatory patient use. The V.A.C.Ulta™ Therapy Unit can be placed on an I.V. pole, bed frame or wheelchair during patient transport.

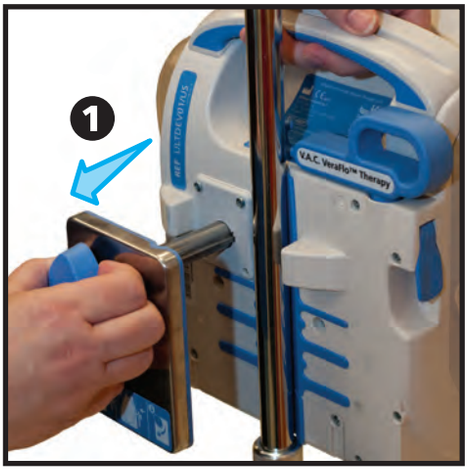
Attaching the V.A.C.Ulta™ Therapy Unit to an I.V. Pole

1. Hold the V.A.C.Ulta™ Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out (**1**).

2. Place the hanger around the I.V. pole and allow the hanger to close, pulling the unit onto the I.V. pole (**2**). Ensure that the pole is in the vertical rubber groove (at both top and bottom) on the rear of the V.A.C.Ulta™ Therapy Unit.

3. Turn the hanger knob to lock the hanger arm in place (**3**). When the arrow symbol on the hanger knob aligns with the lock symbol on the therapy unit, the hanger arm is locked.





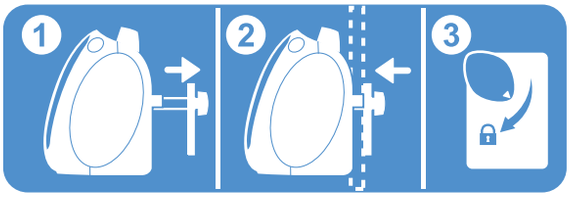
4. Reverse procedure to remove therapy unit.

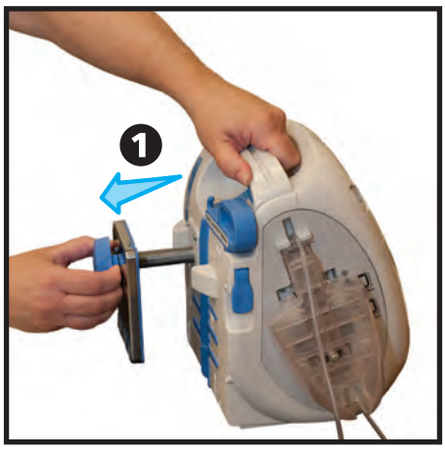
Attaching the V.A.C.Ulta™ Therapy Unit to a Bed Footboard

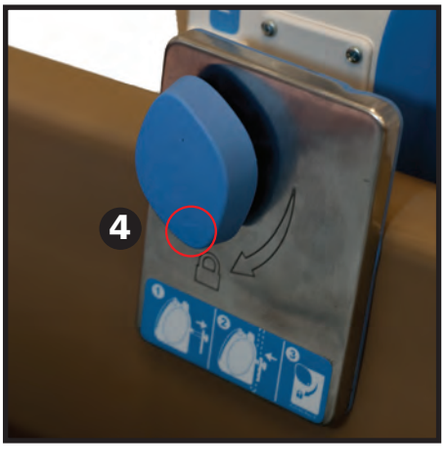
1. Hold the V.A.C.Ulta™ Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out (**1**).

2. Place the hanger over the footboard. Allow the hanger to close, pulling the unit onto the footboard (**2**).

3. Turn the hanger knob to lock the hanger arm in place (**3**). When the arrow symbol on the hanger knob aligns with the lock symbol on the therapy unit, the hanger arm is locked (**4**).

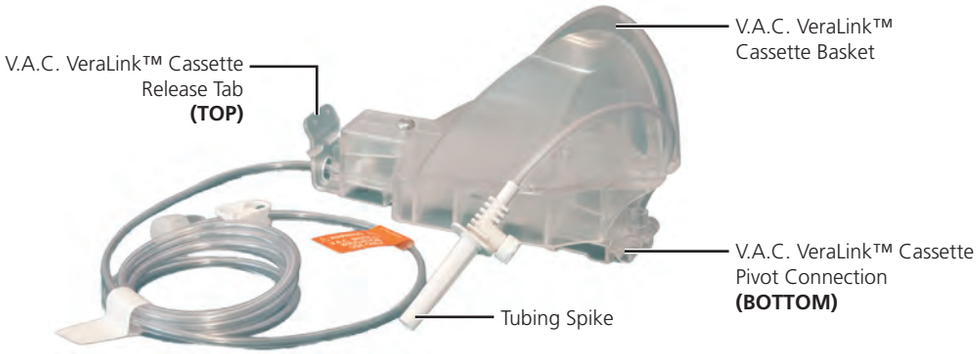






4. Reverse procedure to remove therapy unit.

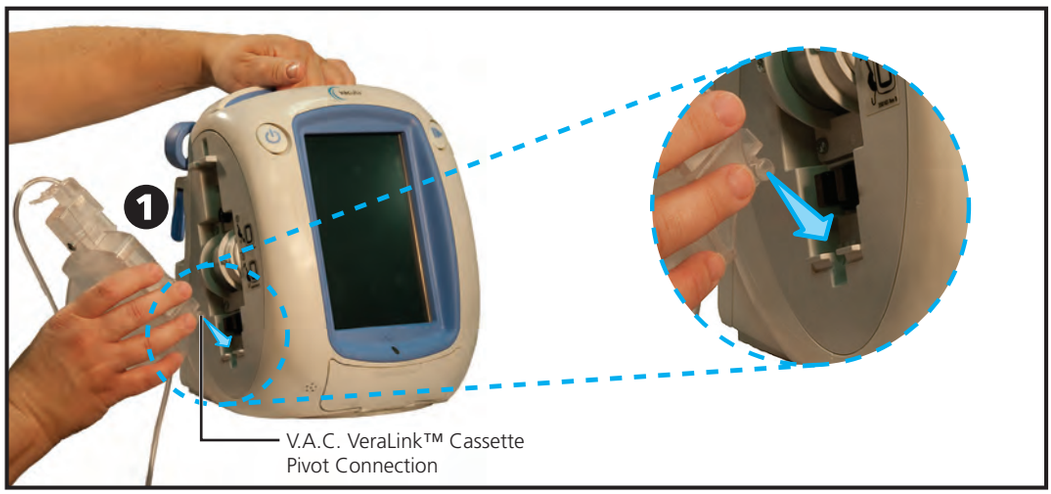
Attaching the V.A.C. VeraLink™ Cassette to the V.A.C.Ulta™ Therapy Unit

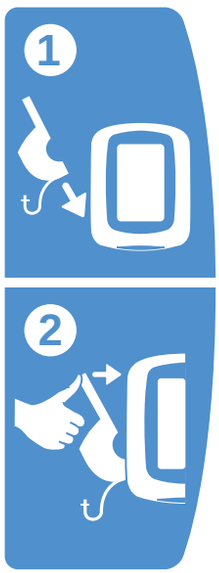

V.A.C. VeraLink™ Cassette Release Tab **(TOP)**
V.A.C. VeraLink™ Cassette Basket
V.A.C. VeraLink™ Cassette Pivot Connection **(BOTTOM)**
Tubing Spike

1. Remove the V.A.C. VeraLink™ Cassette from packaging and insert the pivot connection of the V.A.C. VeraLink™ Cassette (**1**) into the pivot slot on the V.A.C.Ulta™ Therapy Unit (**2**).

2. Pivot the V.A.C. VeraLink™ Cassette Release Tab toward the unit (**3**) and press firmly until it clicks into place.

The V.A.C. VeraLink™ Cassette is designed to fit tight to the therapy unit. Apply very firm pressure to ensure the cassette is properly installed.





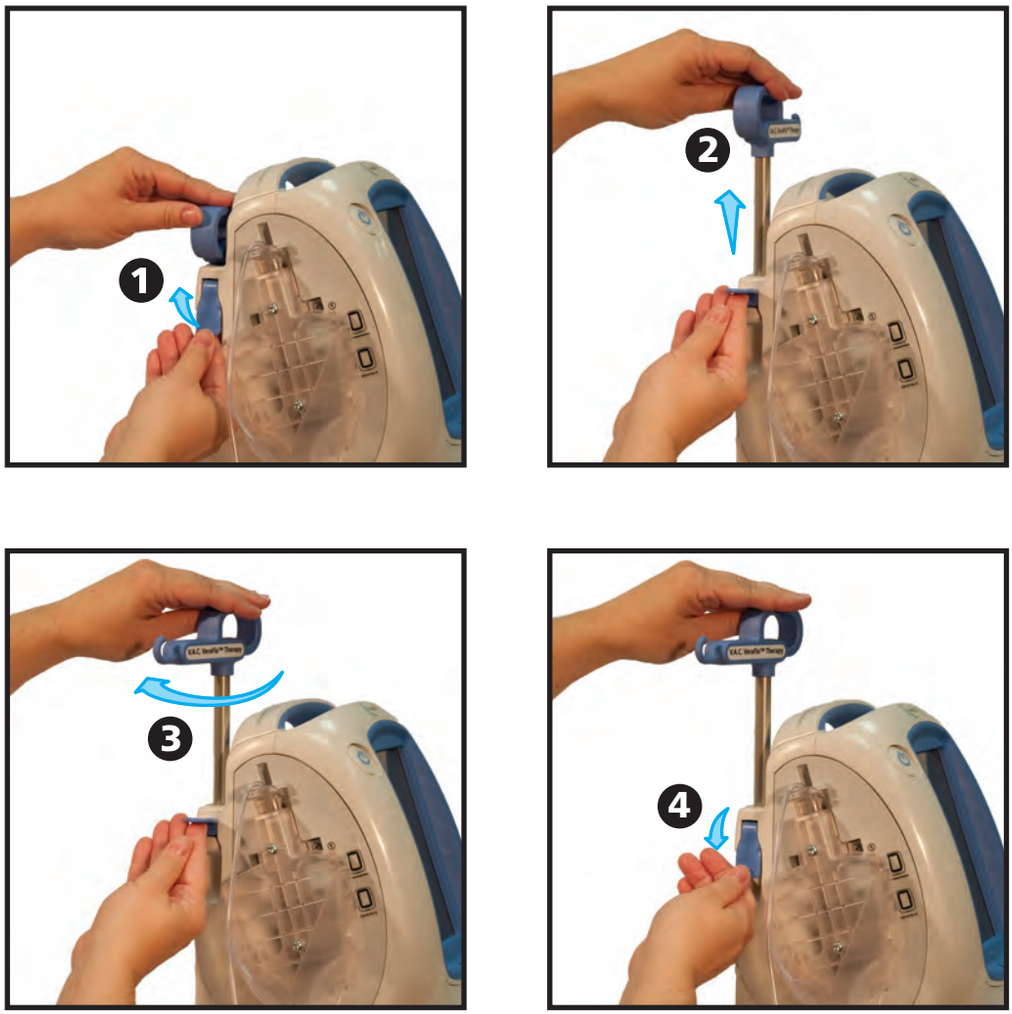
Attaching Solution Bag / Bottle

Extend Solution Container Hanger Arm:

1. Fully lift the solution container hanger arm lock (**1**).

2. Raise solution container hanger arm (**2**) and rotate 180 degrees (**3**).

3. Fully push the solution container hanger arm lock down (**4**) to lock solution container hanger arm in place.



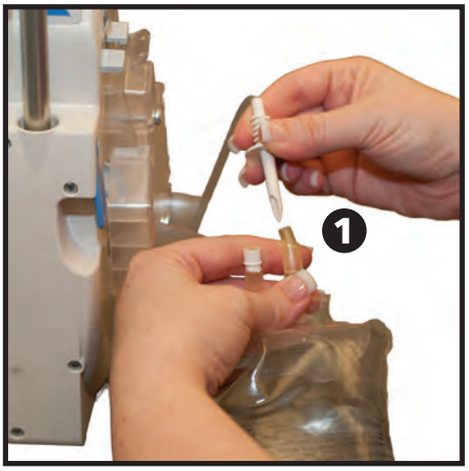
Ensure the solution container arm is secure and locked into place before hanging solution bag / bottle.

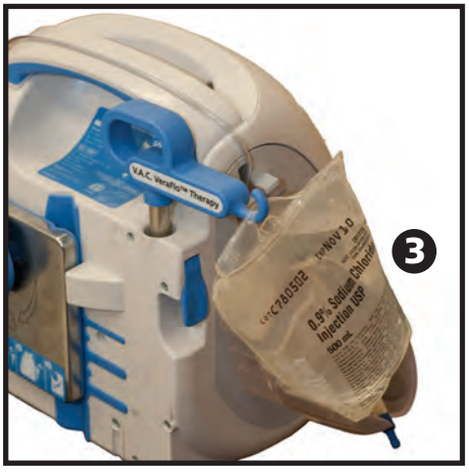
Hang Solution Container Bag / Bottle:

1. Spike solution bag / bottle according to manufacturer's instructions using the V.A.C. VeraLink™ Cassette's tubing spike (**1**).

2. Hang solution bag / bottle from the therapy unit's solution container hanger arm (**2**).

3. Adjust solution container hanger arm while manipulating the bag / bottle to ensure that it is held inside the V.A.C. VeraLink™ Cassette Basket (**3**).





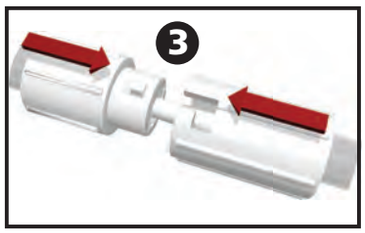
Canister Installation

When selecting canister size, consider the amount of wound exudate and, if delivering V.A.C. VeraFlo™ Therapy, the amount of wound instillation fluid and frequency of instillation.

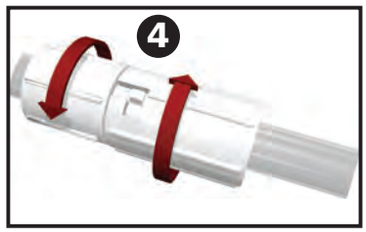
1. Slide the canister into the end of the V.A.C.Ulta™ Therapy Unit (**1**)

2. Push the canister (500 mL shown) firmly into place on the V.A.C.Ulta™ Therapy Unit (**2**). An audible click indicates the canister is fully seated. Ensure the canister is installed directly onto the therapy unit. Do not twist or turn the canister as it is being installed.

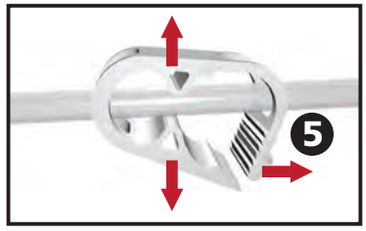
3. Connect the canister tubing to the dressing tubing by pushing the connectors together (**3**).



4. Twist connectors until the locking tabs are fully engaged (**4**).



5. Open all tubing clamps (**5**).



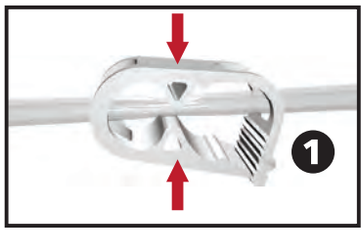
Changing Canister

A canister may be changed under routine conditions or under alarm conditions. Under routine conditions the canister release button will NOT be flashing. When changing the canister do NOT power off the V.A.C.Ulta™ Therapy Unit.

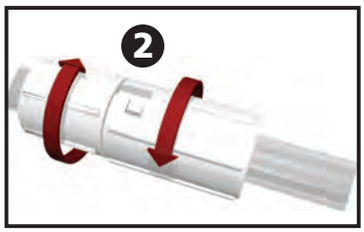
Under alarm conditions, the canister release button (pg. 14) will be flashing, an alarm screen (pg. 88) will be displayed and therapy will be off (unit power remains on).

The canister should be changed when full (the alarm will sound), or at least once a week to control odor.

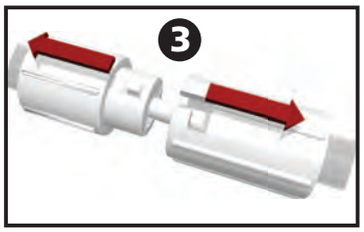
1. Stop therapy by selecting **Start / Stop** on the touch screen. Do not turn power off to the V.A.C.Ulta™ Therapy Unit.
2. Slide both tubing clamps toward the tubing connector.
3. Tightly close both tubing clamps (**1**) to prevent spillage of contents in tubing. Several clicks should be heard.



4. Twist the tubing connectors until the locking tabs are disengaged (**2**).



5. Pull the connector apart (**3**) to disconnect the dressing tubing from the canister tubing.



6. Press the canister release button (**4**).

7. Remove the canister from the therapy unit by lifting and pulling the canister away from the unit.

Dispose of the used canister according to institution and / or local environmental regulations.

8. Install the new canister and reconnect tubing as described in the Canister Installation section (pg. 25) of this user manual.

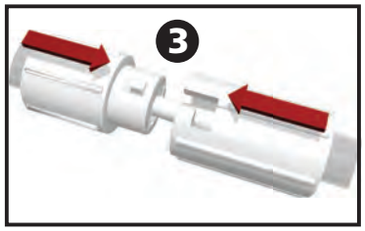
9. Select **Start / Stop** on the touch screen to restart therapy.

Using the 300 mL ActiV.A.C.® Canister with the V.A.C.Ulta™ Therapy Unit

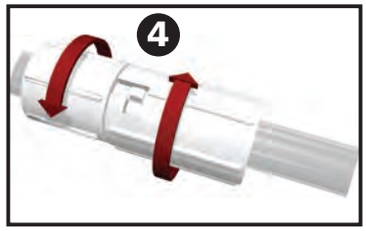
Installing the 300 mL ActiV.A.C.® Canister

1. Push the 300 mL ActiV.A.C.® canister firmly into place on the V.A.C.Ulta™ Therapy Unit (**1** and **2**).

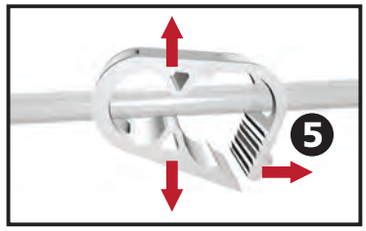
2. Connect the canister tubing to the dressing tubing by pushing the connectors together (**3**).



3. Twist connectors until the locking tabs are fully engaged (**4**).



4. Open all tubing clamps (**5**).

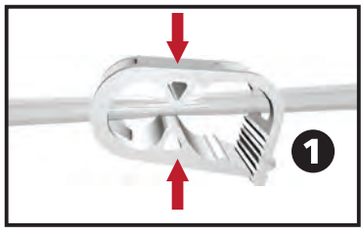


Removing the 300 mL ActiV.A.C.® Canister

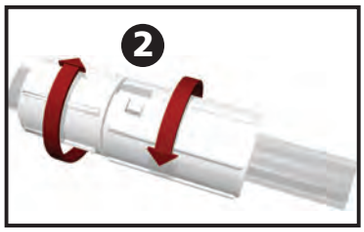
1. Stop therapy by selecting **Start / Stop** on the touch screen. Do not turn power off to the V.A.C.Ulta™ Therapy Unit.

2. Slide both tubing clamps toward the tubing connector.

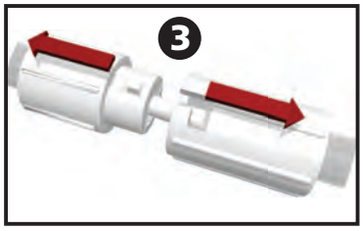
3. Tightly close both tubing clamps (**1**) to prevent spillage of contents in tubing. Several clicks should be heard.



4. Twist the tubing connectors until the locking tabs are disengaged (**2**).



5. Pull the connector apart (**3**) to disconnect the dressing tubing from the canister tubing.



6. Hold the canister firmly and press the Canister Release Button (**4**).

When the canister release button is pressed the 300 mL ActiV.A.C.® Canister is NOT held in place by the cradle of the V.A.C.Ulta™ Therapy Unit. When removing the 300 mL ActiV.A.C.® Canister from the V.A.C.Ulta™ Therapy Unit ensure that the canister is held FIRMLY before pressing the canister release button.

7. Remove the canister from the therapy unit by pulling the canister away from the unit.

Dispose of the used canister according to institution and / or local environmental regulations.

8. Install the new canister and reconnect tubing as described in the Using the 300 mL ActiV.A.C.® Canister with the V.A.C.Ulta™ Therapy Unit section (pg. 28) of this user manual.

9. Select **Start / Stop** on the touch screen to restart therapy.

Operation

This chapter contains instructions for setting and adjusting functions of the V.A.C.Ulta™ Therapy Unit.

Review all sections of this manual prior to product use. Carefully read the Indications, Contraindications, Warnings, and Precautions included with the unit prior to operating the V.A.C.Ulta™ Therapy Unit.

Touch Screen

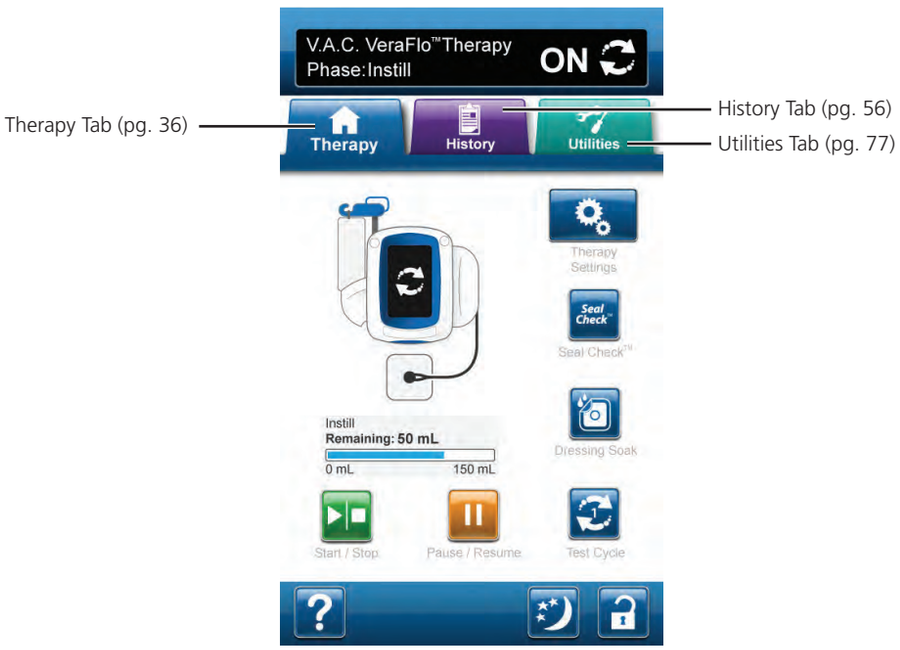
The display on the front of the unit is touch sensitive. The user interface screens will be shown on this display. These screens will display information on current system operations and settings based on the tab selected (**Therapy**, **History** or **Utilities**).

The operation of the touch screen is detailed in the following pages.

The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen.

Touch Screen - Tabs

The touch screen is divided into three sections, each marked by a separate tab. These tabs allow access to the different areas of the V.A.C.Ulta™ Therapy Unit's software.



Therapy Tab - (pg. 36) Use to access the ***Home*** screen and all therapy settings and features. Use the Therapy Tab to configure therapy (V.A.C. VeraFlo™ Therapy or V.A.C.® Therapy).

History Tab - (pg. 56) Use to access to all therapy history for the patient.

Utilities Tab - (pg. 77) Use to set system preferences including language, unit of measure, date, screen brightness, etc. KCI contact information and software version can also be viewed.

Common Touch Screen Buttons

Most screens have one or more common control buttons. These are:

Access Help screens

Activate the **Screen Guard** feature to prevent unintentional changes. This feature should be used when cleaning the touch screen (pg. 108). Select and hold to activate **Settings Lock**. Settings Lock prevents patient access to therapy settings.

Activate Night Mode

Confirm selection

Close pop-up screen

Cancel operation

Return to previous screen

Advance to next screen

Select desired value by selecting or sliding finger / stylus along bar. Use **+** / **-** to adjust above or below values shown.

Power the V.A.C.Ulta™ Therapy Unit On or Off

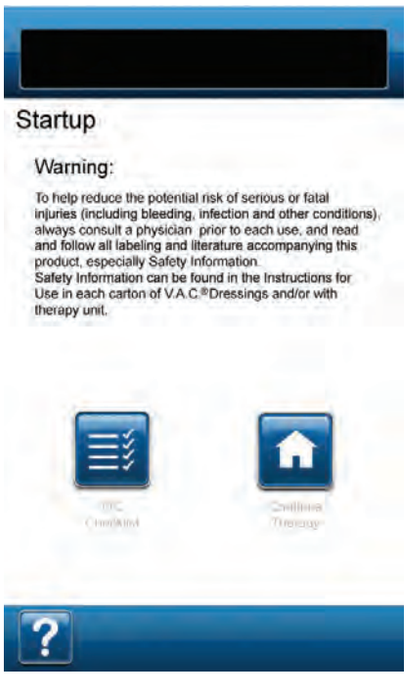
The **Power** button is located in the upper left hand corner on the front of the unit (pg. 14). Press and hold the **Power** button until the light comes on to turn the V.A.C.Ulta™ Therapy Unit on. The unit will go through a self-check routine and then present the ***Startup*** screen. Press and hold the **Power** button until the display turns off to turn the V.A.C.Ulta™ Therapy Unit off.

The ***Startup*** screen will be displayed one of two ways:

Startup
Warning:
To help reduce the potential risk of serious or fatal injuries (including bleeding, infection and other conditions), always consult a physician prior to each use, and read and follow all labeling and literature accompanying this product, especially Safety Information.
Safety Information can be found in the Instructions for Use in each carton of V.A.C.®Dressings and/or with therapy unit.

The first time the V.A.C.Ulta™ Therapy System is used following a quality checklist inspection and cleaning, the ***Startup*** screen will display **New Patient**.

New Patient - Select **New Patient** to accept the **Warning** and proceed to new therapy set up to configure **V.A.C. VeraFlo™ Therapy** (pg. 35) or **V.A.C.® Therapy** (pg. 41) for the first time.


Startup
Warning:
To help reduce the potential risk of serious or fatal injuries (including bleeding, infection and other conditions), always consult a physician prior to each use, and read and follow all labeling and literature accompanying this product, especially Safety Information.
Safety Information can be found in the Instructions for Use in each carton of V.A.C.®Dressings and/or with therapy unit.

If the V.A.C.Ulta™ Therapy Unit has been previously set up and the unit is power cycled (turned off then back on), the ***Startup*** Screen will display **Continue Therapy** and **QC Checklist**.

Continue Therapy - Select to accept **Warning** and return to previously used therapy ***Home*** screen (pg. 39 or 45).

QC Checklist - Select to accept **Warning** and proceed to Quality Checklist inspection process.

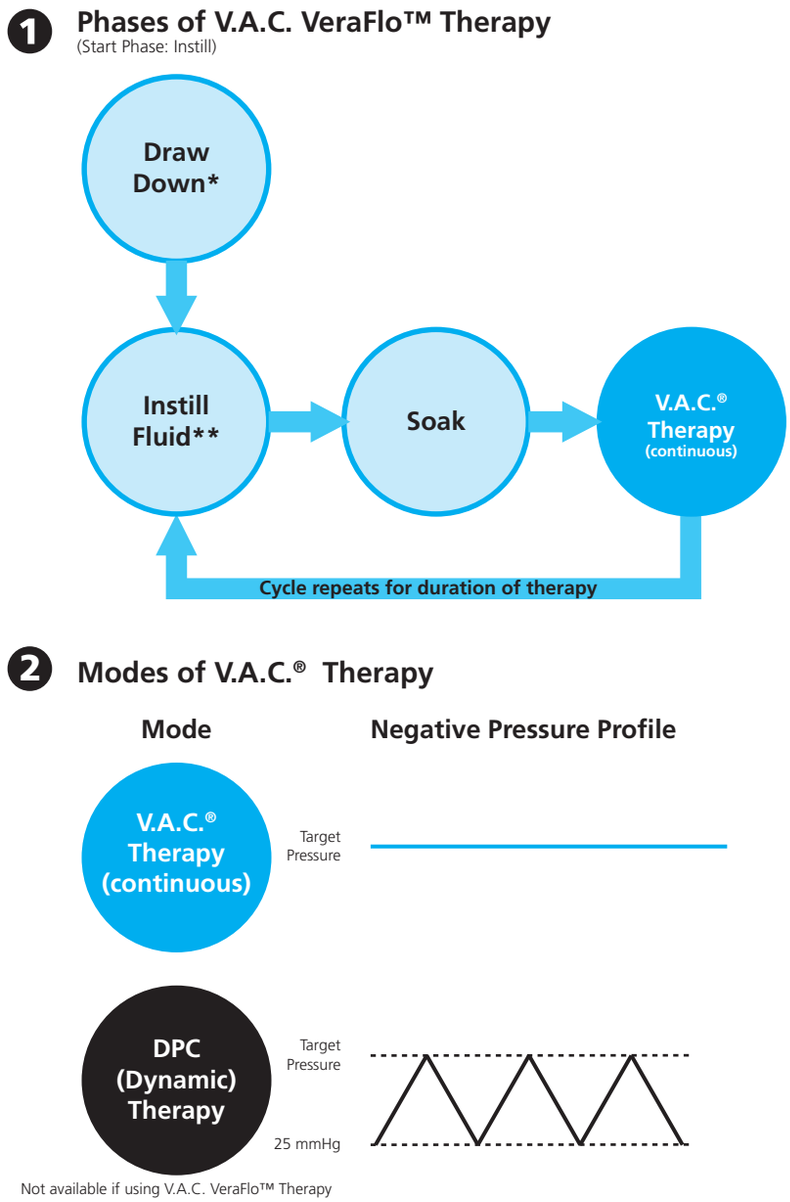
Accompanying Service Documentation is required to use QC Checklist functions. Please contact KCI for more information.

V.A.C.Ulta™ Therapy System - Therapy Options

The V.A.C.Ulta™ Therapy System can be used with two different therapies depending on physician orders:

V.A.C. VeraFlo™ Therapy: (**1**) Consists of negative pressure wound therapy (V.A.C.® Therapy) coupled with controlled delivery and drainage of topical wound irrigation, treatment solutions and suspensions over the wound bed.

V.A.C.® Therapy: (**2**) Consists of negative pressure wound therapy alone.



* Seal Check™ Leak Detector

** Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VeraFlo™ Therapy.

V.A.C. VeraFlo™ Therapy Configuration - Overview

The following flow chart shows the basic steps required to configure V.A.C. VeraFlo™ Therapy. Refer to the following pages for detailed information about individual screens and options.

Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.

Settings displayed will vary depending on settings defined by user.

Configure V.A.C. VeraFlo™ Therapy (first time use)

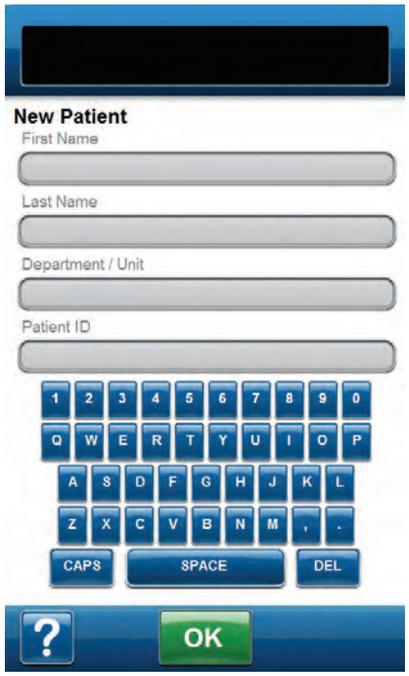
Select **New Patient** on the ***Startup*** screen to configure the V.A.C.Ulta™ Therapy unit for a new patient.

V.A.C. VeraFlo™ Therapy User Interface Screens - Therapy Tab

The following section describes how to configure V.A.C. VeraFlo™ Therapy.

New Patient Screen

Use this screen to enter the patient's information into the V.A.C.Ulta™ Therapy Unit.


New Patient
First Name
Last Name
Department / Unit
Patient ID
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M , .
CAPS
SPACE
DEL
OK

Use the onscreen keyboard to enter the following:

- Patient's First Name
- Patient's Last Name
- Patient's Department / Unit
- Patient's (Identification) ID

Once this information has been entered, select **OK** to continue to the ***Choose Therapy*** screen.

At least one character must be entered into each entry row.

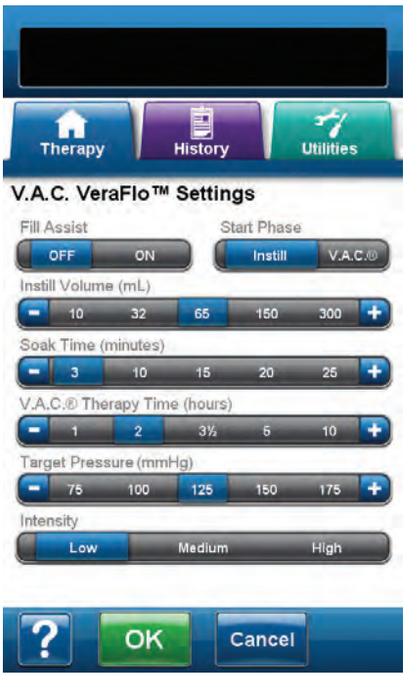
Choose Therapy Screen

Use this screen to select which therapy the V.A.C.Ulta™ Therapy unit will deliver.

Therapy
History
Utilities
Choose Therapy
Carefully review safety information, instructions for use and the V.A.C® Therapy Clinical Guidelines before proceeding. Always follow physician orders.
V.A.C. VeraFlo Therapy
V.A.C. Therapy

Select **V.A.C. VeraFlo™ Therapy** to continue to the ***V.A.C. VeraFlo™ Settings*** screen.

V.A.C. VeraFlo™ Settings Screen

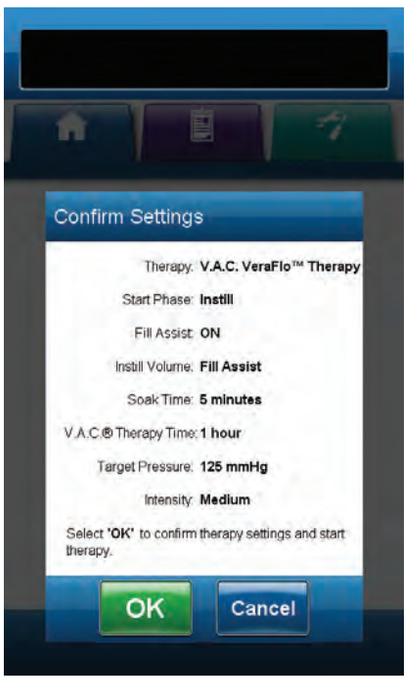


Use this screen to configure the V.A.C.Ulta™ Therapy Unit to deliver V.A.C. VeraFlo™ Therapy:

- **Fill Assist** - Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VeraFlo™ Therapy (pg. 50).
- **Start Phase** - Sets first phase of V.A.C. VeraFlo™ Therapy.
- **Instill Volume (mL)** - Solution volume required to fill wound when dressing is applied. Selected volume will be instilled during each Instill phase of V.A.C. VeraFlo™ Therapy. When the Fill Assist slider is set to ON, this selection will not be available. Refer to the Fill Assist section (pg. 50) for more information.

Overfilling wound may compromise dressing seals.

- **Soak Time (minutes)** - Time instilled solution will remain in wound during each soak phase of V.A.C. VeraFlo™ Therapy.
- **V.A.C.® Therapy Time (hours)** - Duration of time that negative pressure will be applied during each V.A.C.® Therapy phase of V.A.C. VeraFlo™ Therapy.
- **Target Pressure (mmHg)** - Prescribed negative pressure level for V.A.C.® Therapy phase.
- **Intensity** - Related to the time it takes to reach the target pressure after the initiation of therapy. The lower the intensity setting, the slower the target pressure will be reached. It is recommended that new patients begin therapy at the lowest intensity setting as this allows for slower increase of negative pressure once the foam is compressed in the wound. The intensity can remain at the minimum setting throughout the entire length of treatment, if desired.



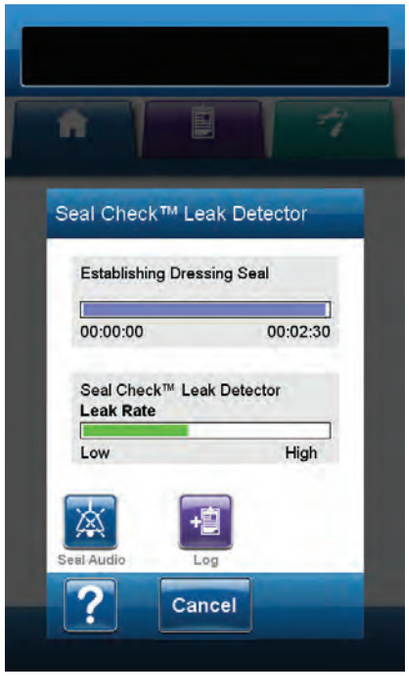
1. Select desired value by selecting or sliding finger / stylus along bar. Use **+** / **-** to adjust above or below values shown.

2. Once all settings have been entered, select **OK** to continue to the ***Confirm Settings*** screen. This screen allows the user to review the therapy settings that were selected on the ***V.A.C. VeraFlo™ Settings*** screen.

3. Select **OK** to initiate therapy and continue to the ***Seal Check™ Leak Detector*** screen for V.A.C. VeraFlo™ Therapy.

4. Select **Cancel** to return to the ***V.A.C. VeraFlo™ Settings*** screen to make any required adjustments.

Seal Check™ Leak Detector Screen - V.A.C. VeraFlo™ Therapy



Use this screen to view the current status of the Drawdown Phase of V.A.C. VeraFlo™ Therapy while dressing seal is being established. Use this screen also to access the ***Log*** screen and the Seal Check™ Leak Detector audio control. For more information on the Seal Check™ Leak Detector, refer to pg. 53.

Seal Audio - Audible tone used to find and repair leaks. Select to turn seal audio tone on or off.

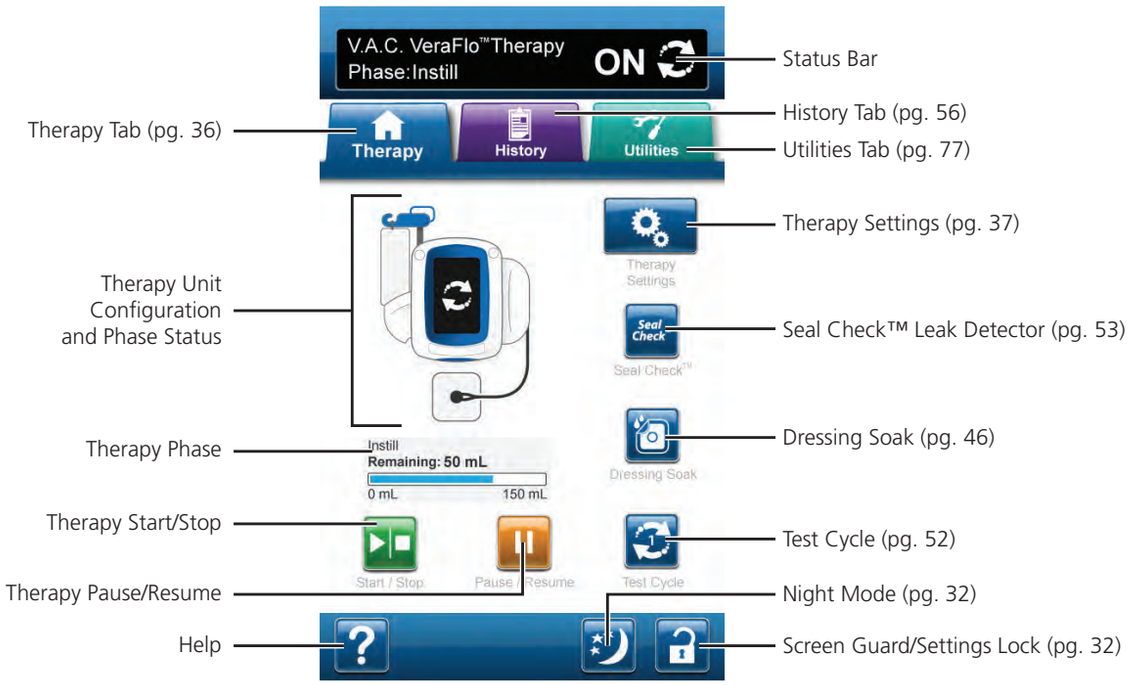
Log - Used to record disposable component change (pg. 55).

Drawdown will take approximately three minutes to establish seals. During this drawdown, observe the dressing for leaks. Ensure that disposable changes are logged using **Log** (pg. 55).

Once the Drawdown phase is complete the unit will transitition to the ***Home*** screen or ***Fill Assist*** screen (pg. 50) depending on therapy settings.

Home Screen - V.A.C. VeraFlo™ Therapy

The ***Home*** screen is the main screen displayed by the V.A.C.Ulta™ Therapy Unit during therapy. Use to access important information about the status of the therapy cycle.



Therapy phase and status (ON, OFF or PAUSED) will be displayed in the status bar at the top of the screen. The current therapy phase will also appear under the icon of the therapy unit along with time or fluid amount (during the instillation phase) remaining.

The following options are available from the ***Home*** screen:

Therapy Settings - Use to select and configure the prescribed therapy that the V.A.C.Ulta™ Therapy Unit will deliver.

Seal Check™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (pg. 53).

Dressing Soak - Use to soak the dressing with solution in preparation for a dressing change (pg. 46).

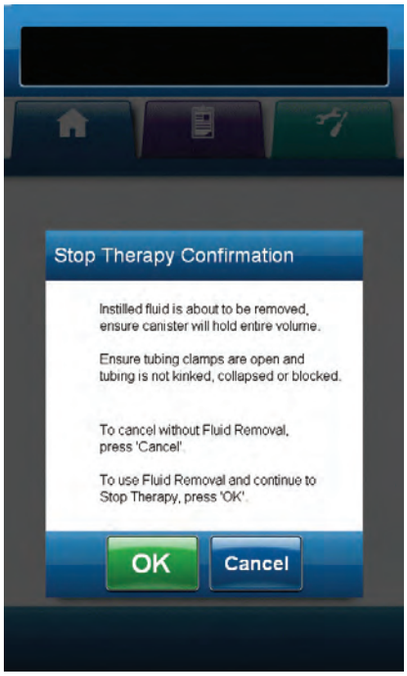
Test Cycle - Use to complete an abbreviated V.A.C. VeraFlo™ Therapy cycle. Each phase of the cycle will be tested to ensure system is set up and functioning correctly (pg. 52).

Start / Stop - Use to start or stop therapy.

Pause / Resume - Use to pause or resume therapy.

Help - Use to access the V.A.C.Ulta™ Therapy Unit's on-screen help features.

Stop Therapy Confirmation

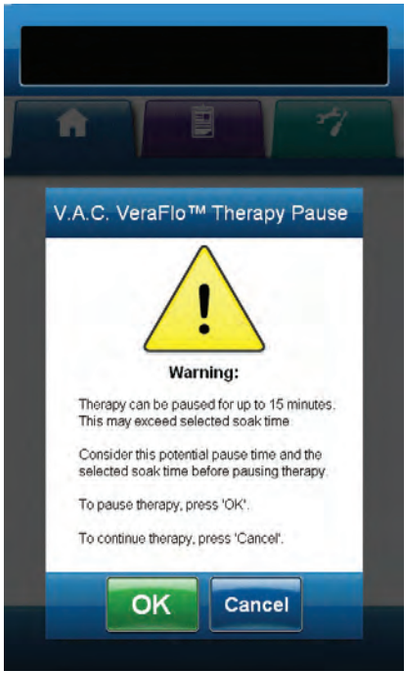

Stop Therapy Confirmation
Instilled fluid is about to be removed, ensure canister will hold entire volume.
Ensure tubing clamps are open and tubing is not kinked, collapsed or blocked.
To cancel without Fluid Removal, press 'Cancel'.
To use Fluid Removal and continue to Stop Therapy, press 'OK'.
OK
Cancel

1. Once therapy has been started, select **Start / Stop** from the ***Home*** screen to continue to the ***Stop Therapy Confirmation*** screen.

2. Select **OK** to stop therapy. Select **Cancel** to return to the ***Home*** screen without stopping therapy.

Instilled fluid will be removed; ensure canister can hold the entire volume. Ensure tubing clamps are open and tubing is not kinked, collapsed or blocked.

V.A.C. VeraFlo™ Therapy Paused


V.A.C. VeraFlo™ Therapy Pause
Warning:
Therapy can be paused for up to 15 minutes. This may exceed selected soak time.
Consider this potential pause time and the selected soak time before pausing therapy.
To pause therapy, press 'OK'.
To continue therapy, press 'Cancel'.
OK
Cancel

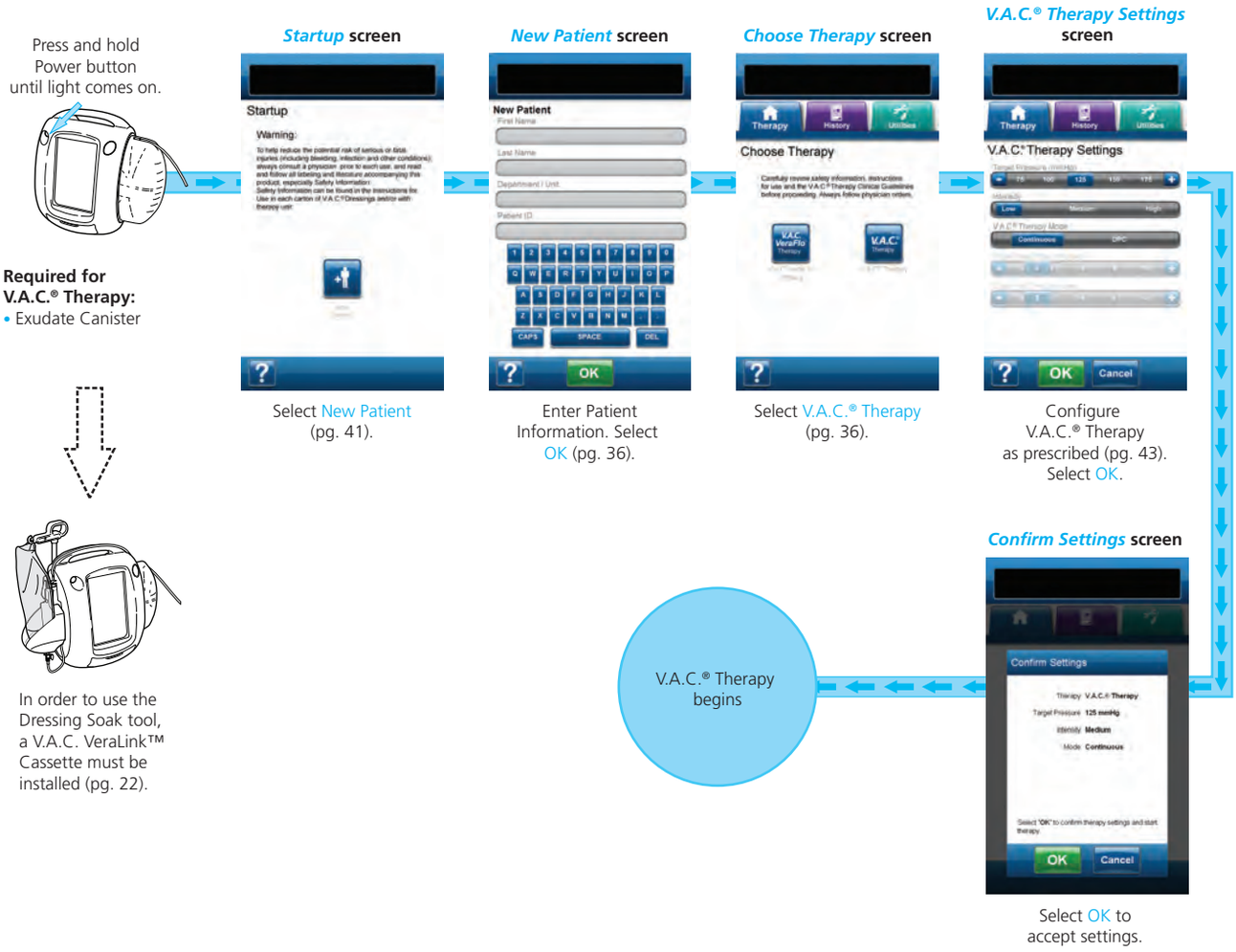
1. Once therapy has been started, select **Pause / Resume** from the ***Home*** screen to continue to the ***V.A.C. VeraFlo™ Therapy Pause*** screen.

2. Select **OK** to pause therapy. Select **Cancel** to return to the ***Home*** screen without pausing therapy.

Therapy can be paused for up to 15 minutes. This may exceed selected soak time. Consider this pause time and the selected soak time before pausing therapy.

V.A.C.® Therapy Configuration - Overview

The following flow chart shows the basic steps required to configure V.A.C.® Therapy. Refer to the following pages for detailed information about individual screens and options.



Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.

Settings displayed will vary depending on settings defined by user.

Configure V.A.C.® Therapy (first time use)

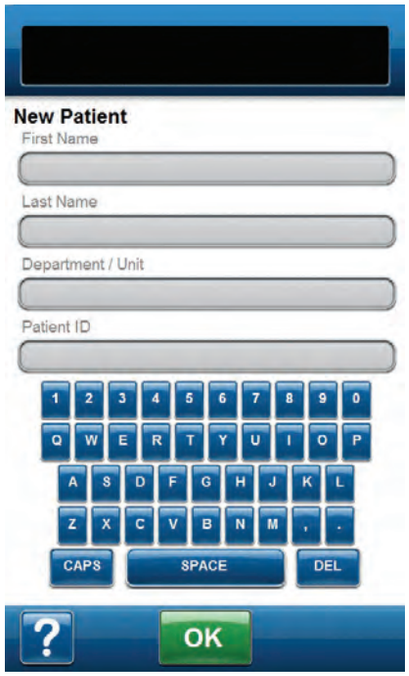
Select **New Patient** on the ***Startup*** screen to configure the V.A.C.Ulta™ Therapy Unit for a new patient.

V.A.C.® Therapy User Interface Screens - Therapy Tab

The following section describes how to configure V.A.C.® Therapy.

New Patient Screen

Use this screen to enter the patient's information into the V.A.C.Ulta™ Therapy Unit.


New Patient
First Name
Last Name
Department / Unit
Patient ID
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M , .
CAPS
SPACE
DEL
OK

Use the onscreen keyboard to enter the following:

- Patient's First Name
- Patient's Last Name
- Patient's Department / Unit
- Patient's (Identification) ID.

Once this information has been entered, select **OK** to continue to the ***Choose Therapy*** screen.

At least one character must be entered into each entry row.

Choose Therapy Screen

Use this screen to select which therapy the V.A.C.Ulta™ Therapy Unit will deliver.

Therapy
History
Utilities
Choose Therapy
Carefully review safety information, instructions for use and the V.A.C.® Therapy Clinical Guidelines before proceeding. Always follow physician orders.
V.A.C. VeraFlo Therapy
V.A.C.® Therapy

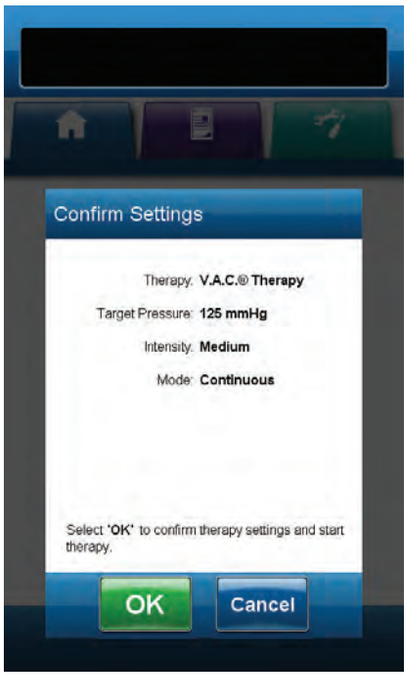
Select **V.A.C.® Therapy** to continue to the ***V.A.C.® Therapy Settings*** screen.

V.A.C.® Therapy Settings Screen

This screen allows the user to configure the V.A.C.Ulta™ Therapy Unit to deliver V.A.C.® Therapy:

- **Target Pressure (mmHg)** - Prescribed negative pressure level for V.A.C.® Therapy.
- **Intensity** - Related to the time it takes to reach the target pressure after the initiation of therapy. The lower the intensity setting, the slower the target pressure will be reached. It is recommended that new patients begin therapy at the lowest intensity setting as this allows for slower increase of negative pressure once the foam is compressed in the wound. The intensity can remain at the minimum setting throughout the entire length of treatment, if desired.
- **V.A.C.® Therapy Mode** - Available modes include **Continuous** and **DPC** (Dynamic Pressure Control™ Therapy). Continuous provides constant negative pressure at selected Target Pressure. DPC (Dynamic Pressure Control™ Therapy) provides negative pressure between preset low pressure (25 mmHg) and selected Target Pressure.

1. Select desired value by selecting or sliding finger / stylus along bar. Use **+** / **-** to adjust above or below values shown.

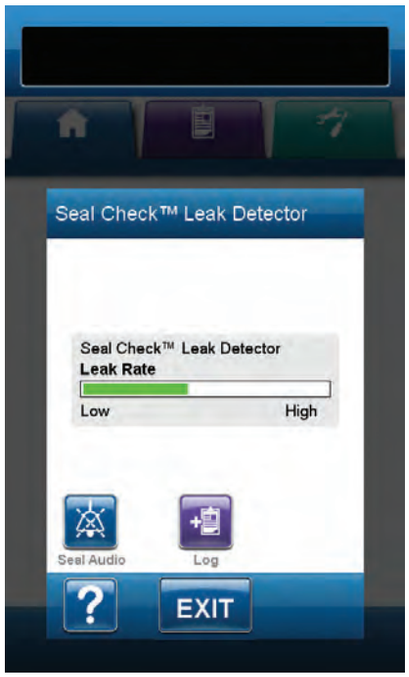


2. Once all settings have been entered, select **OK** to continue to the ***Confirm Settings*** screen. This screen allows the user to review the therapy settings that were selected on the ***V.A.C.® Therapy Settings*** screen.

3. Select **OK** to initiate therapy and continue to the ***Seal Check™ Leak Detector*** screen for V.A.C.® Therapy.

4. Select **Cancel** to return to the ***V.A.C.® Therapy Settings*** screen to make any required adjustments.

Seal Check™ Leak Detector Screen - V.A.C.® Therapy



Use this screen to view the Seal Check™ Leak Detector. Also access the ***Log*** screen and the Seal Check™ Leak Detector audio control. For more information on the Seal Check™ Leak Detector, refer to pg. 53.

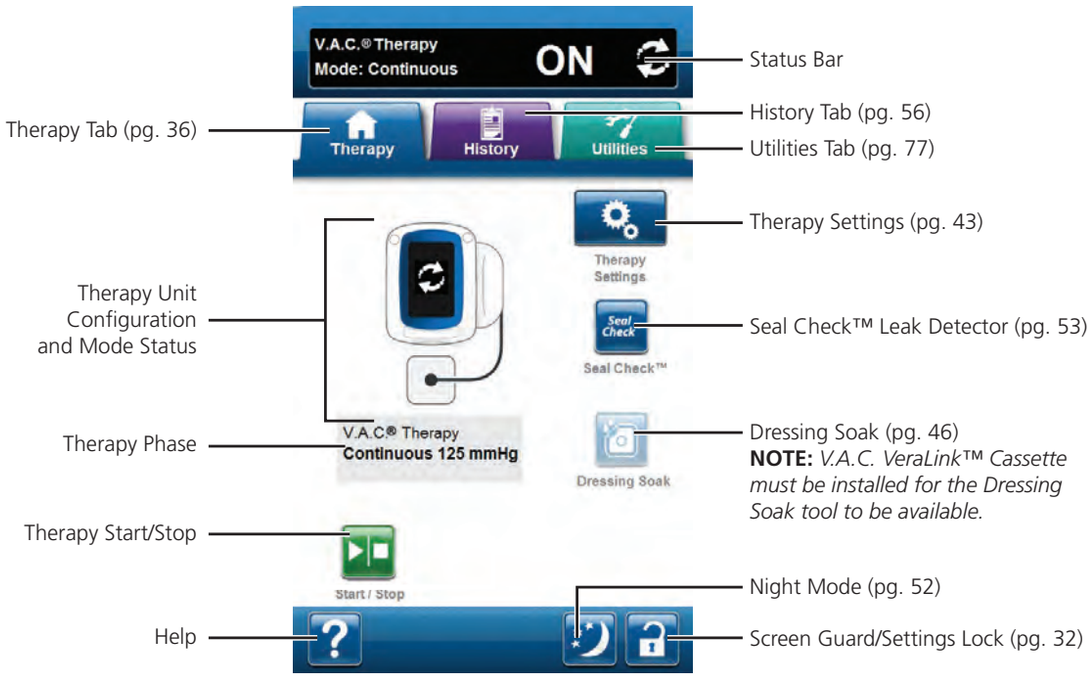
Seal Audio - Audible tone used to find and repair leaks. Select to turn seal audio tone on or off.

Log - Used to record disposable component changes (pg. 55).

Select **Exit** to transition to the ***Home*** screen. The unit will automatically transition to the ***Home*** screen after approximately two minutes of screen inactivity.

Home Screen - V.A.C.® Therapy

The ***Home*** screen is the main screen displayed by the V.A.C.Ulta™ Therapy Unit during therapy. Use to access important information about the status of therapy.



Therapy mode and status (ON, OFF or PAUSED) will be displayed in the status bar at the top of the screen. The current therapy mode will also appear under the icon of the therapy unit along with configured pressure.

The following options are available from the ***Home*** screen:

Therapy Settings - Use to select and configure the prescribed therapy that the V.A.C.Ulta™ Therapy Unit will deliver.

Seal Check™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (pg. 53).

Dressing Soak - Use to soak the dressing with solution in preparation for a dressing change (pg. 46).

The V.A.C. VeraLink™ Cassette (pg. 22) must be installed for the Dressing Soak to be available.

Start / Stop - Use to start or stop therapy.

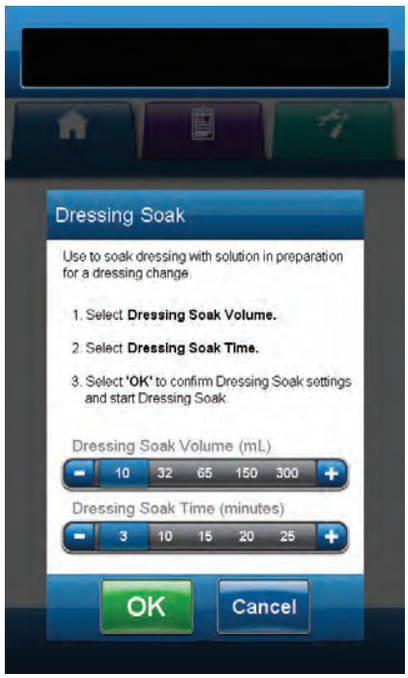
Help - Use to access to the V.A.C.Ulta™ Therapy Unit's on-screen help features.

Dressing Soak

Use to soak the dressing with solution in preparation for a dressing change.

If the Dressing Soak tool is available for selection, the Dressing Soak icon will be blue.

If operating in V.A.C.® Therapy mode, the V.A.C. VeraLink™ Cassette (pg. 22) must be installed for the Dressing Soak tool to be available.


Dressing Soak
Use to soak dressing with solution in preparation for a dressing change.
1. Select Dressing Soak Volume.
2. Select Dressing Soak Time.
3. Select 'OK' to confirm Dressing Soak settings and start Dressing Soak.
Dressing Soak Volume (mL)
10 32 65 150 300
Dressing Soak Time (minutes)
3 10 15 20 25
OK
Cancel

Dressing Soak selected while therapy is idle:

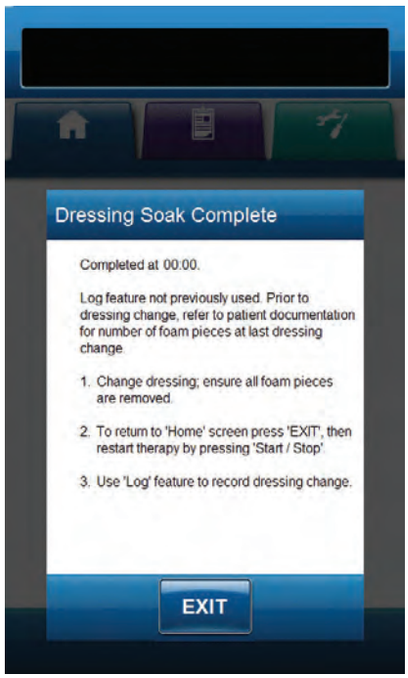
1. Ensure that both the V.A.C.® Therapy tube and Instillation tube are properly connected.
2. Ensure that all four tubing clamps are open.
3. Ensure that the V.A.C. VeraLink™ Cassette is properly installed (pg. 22).
4. Ensure that the canister has adequate capacity remaining for the dressing change.

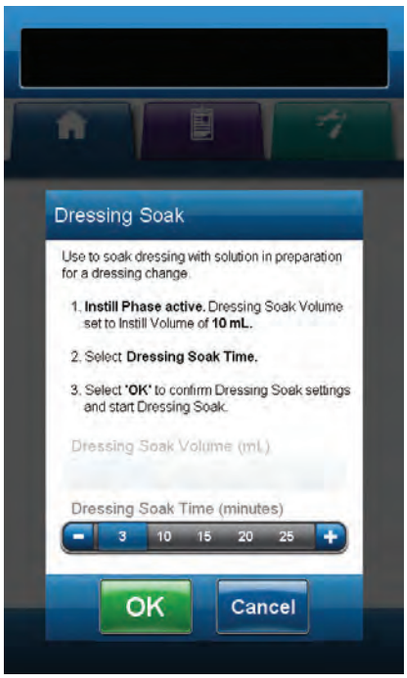
5. Select **Dressing Soak** from the ***Home*** screen to continue to the ***Dressing Soak*** screen.
6. Select the target **Dressing Soak Volume (mL)**.
7. Select the target **Dressing Soak Time (minutes)**.

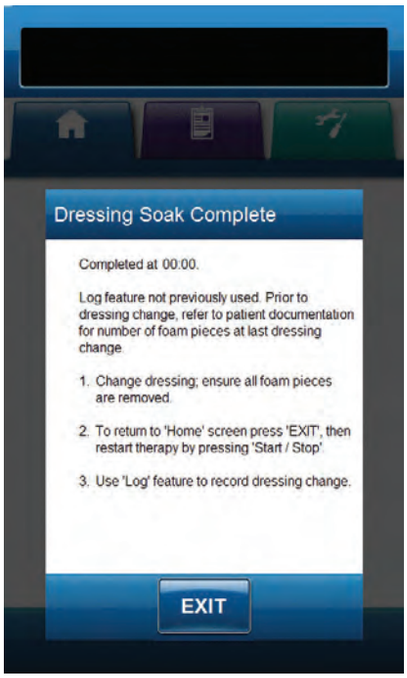
8. Select **OK** to confirm settings and return to the ***Home*** screen.
9. The V.A.C.Ulta™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy will be displayed in the status bar (pg. 39 or 45) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the Instill phase) remaining.
10. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.

11. Select **Exit** to return to the ***Home*** screen.

Refer to the appropriate dressing Instructions for Use for Safety Information and Instructions for changing the dressing.


Dressing Soak Complete
Completed at 00:00.
Log feature not previously used. Prior to dressing change, refer to patient documentation for number of foam pieces at last dressing change.
1. Change dressing; ensure all foam pieces are removed.
2. To return to 'Home' screen press 'EXIT', then restart therapy by pressing 'Start / Stop'.
3. Use 'Log' feature to record dressing change.
EXIT


Dressing Soak
Use to soak dressing with solution in preparation for a dressing change.
1. Instill Phase active. Dressing Soak Volume set to Instill Volume of 10 mL.
2. Select Dressing Soak Time.
3. Select 'OK' to confirm Dressing Soak settings and start Dressing Soak.
Dressing Soak Volume (mL)
Dressing Soak Time (minutes)
3 10 15 20 25
OK
Cancel


Dressing Soak Complete
Completed at 00:00.
Log feature not previously used. Prior to dressing change, refer to patient documentation for number of foam pieces at last dressing change.
1. Change dressing; ensure all foam pieces are removed.
2. To return to 'Home' screen press 'EXIT', then restart therapy by pressing 'Start / Stop'
3. Use 'Log' feature to record dressing change.
EXIT

Dressing Soak selected during Instill Phase:

1. Select **Dressing Soak** from the ***Home*** screen to continue to the ***Dressing Soak*** screen.

2. Select the target **Dressing Soak Time (minutes)**.

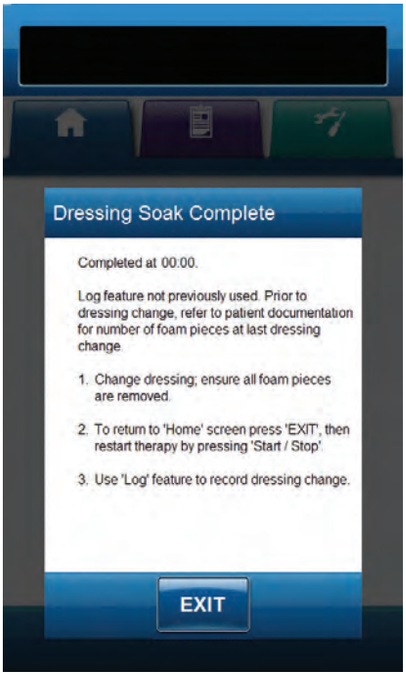
3. Select **OK** to confirm settings and return to the ***Home*** screen.

4. The V.A.C.Ulta™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy will be displayed in the status bar (pg. 39 or 45) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the Instill phase) remaining.

5. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.

6. Select **Exit** to return to the ***Home*** screen.

Refer to the appropriate dressing Instructions for Use for Safety Information and Instructions for changing the dressing.


Dressing Soak Complete
Completed at 00:00.
Log feature not previously used. Prior to dressing change, refer to patient documentation for number of foam pieces at last dressing change.
1. Change dressing; ensure all foam pieces are removed.
2. To return to 'Home' screen press 'EXIT', then restart therapy by pressing 'Start / Stop'.
3. Use 'Log' feature to record dressing change.
EXIT

Dressing Soak selected during Soak Phase:

1. Select **Dressing Soak** from the ***Home*** screen to begin Dressing Soak.

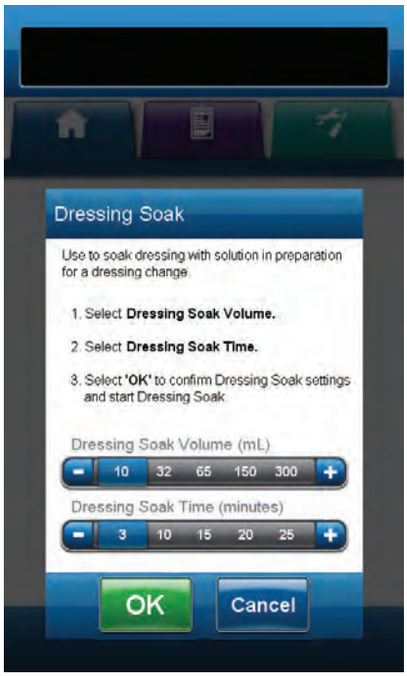
2. The V.A.C.Ulta™ Therapy Unit will complete the Soak and fluid removal phases. Therapy will be displayed in the status bar (pg. 39 or 45) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the Instill phase) remaining.

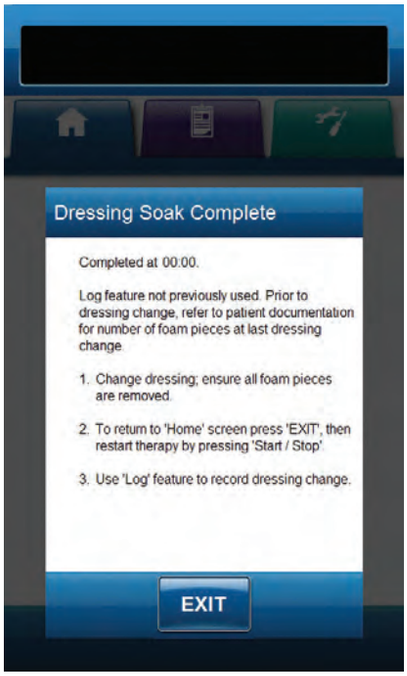
3. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.

EXIT

4. Select **Exit** to return to the ***Home*** screen.

Refer to the appropriate dressing Instructions for Use for Safety Information and Instructions for changing the dressing.


Dressing Soak
Use to soak dressing with solution in preparation for a dressing change.
1. Select Dressing Soak Volume.
2. Select Dressing Soak Time.
3. Select 'OK' to confirm Dressing Soak settings and start Dressing Soak.
Dressing Soak Volume (mL)
10 32 65 150 300
Dressing Soak Time (minutes)
3 10 15 20 25
OK
Cancel


Dressing Soak Complete
Completed at 00:00.
Log feature not previously used. Prior to dressing change, refer to patient documentation for number of foam pieces at last dressing change.
1. Change dressing; ensure all foam pieces are removed.
2. To return to 'Home' screen press 'EXIT', then restart therapy by pressing 'Start / Stop'.
3. Use 'Log' feature to record dressing change.
EXIT

Dressing Soak selected during V.A.C.® Therapy Phase:

1. Ensure that the Instillation tube is properly connected.
2. Ensure that all four tubing clamps are open.
3. Ensure that the V.A.C. VeraLink™ Cassette is properly installed (pg. 22).
4. Ensure that the exudate canister has adequate capacity remaining for the dressing change.

5. Select **Dressing Soak** from the ***Home*** screen to continue to the ***Dressing Soak*** screen.
6. Select the target **Dressing Soak Volume (mL)**.
7. Select the target **Dressing Soak Time (minutes)**.

8. Select **OK** to confirm settings and return to the ***Home*** screen.
9. The V.A.C.Ulta™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy phase will be displayed in the status bar (pg. 39 or 45) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the Instill phase) remaining.
10. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.

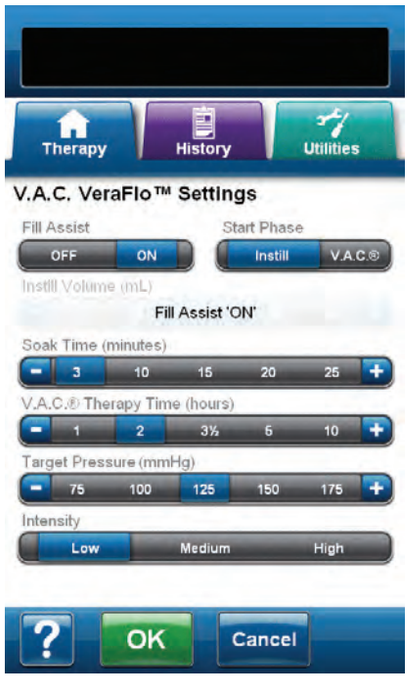
11. Select **Exit** to return to the ***Home*** screen.

Refer to the appropriate dressing Instructions for Use for Safety Information and Instructions for changing the dressing.

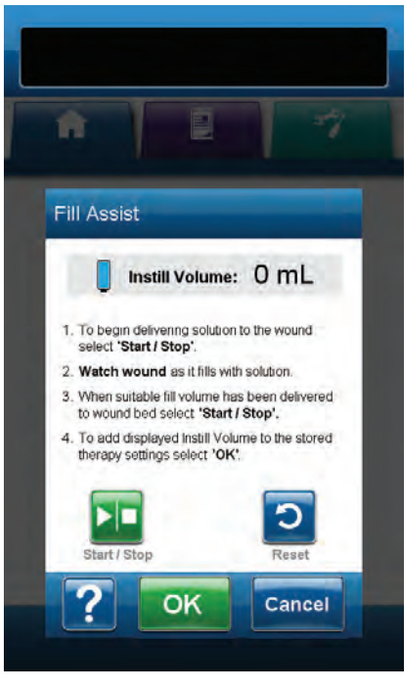
Fill Assist

Fill Assist helps user determine the correct instill volume to use during the Instill Phase of a V.A.C. VeraFlo™ Therapy cycle.

Allows user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume for each instill phase. If correct instill volume is already known, select Fill Assist **OFF** to use Instill Volume selection bar.



1. Ensure that both the V.A.C.® Therapy tube and Instillation tube are properly connected.
2. Ensure that all four tubing clamps are open.
3. Ensure that the V.A.C. VeraLink™ Cassette is properly installed (pg. 22).
4. Ensure that the exudate canister is properly installed (pg. 25).
5. Verify that the **Fill Assist** slider is set to **ON** (default).
6. Select the **Start Phase**.
7. Select the **Soak Time (minutes)**.
8. Select the **V.A.C.® Therapy Time (hours)**.
9. Select the **Target Pressure (mmHg)**.
10. Select the **Intensity**.


Fill Assist
Instill Volume: 0 mL
1. To begin delivering solution to the wound select 'Start / Stop'.
2. Watch wound as it fills with solution.
3. When suitable fill volume has been delivered to wound bed select 'Start / Stop'.
4. To add displayed Instill Volume to the stored therapy settings select 'OK'.
Start / Stop
Reset
OK
Cancel

11. Select **OK** to confirm settings and continue to the ***Fill Assist*** screen.

The therapy unit will automatically transition to the *Seal Check™ Leak Detector* screen to begin drawing down the dressing and will continue to apply negative pressure until the Start / Stop is selected on the Fill Assist screen.

12. Drawdown will take approximately three minutes to establish dressing seal. During the drawdown, observe the dressing for leaks. Ensure that disposable changes are logged using the **Log** tool (pg. 55).

13. Select **Start / Stop** on the ***Fill Assist*** screen to begin delivering solution to the wound.

During the use of Fill Assist it is possible to exceed the soak time for a solution. Consider elapsed time in comparison to the selected soak time while using this tool.

14. **Monitor the wound as it fills with solution.**

15. Select **Start / Stop** again to stop solution delivery when suitable fill volume has been delivered to the wound bed.

Overfilling wound may compromise dressing seals.

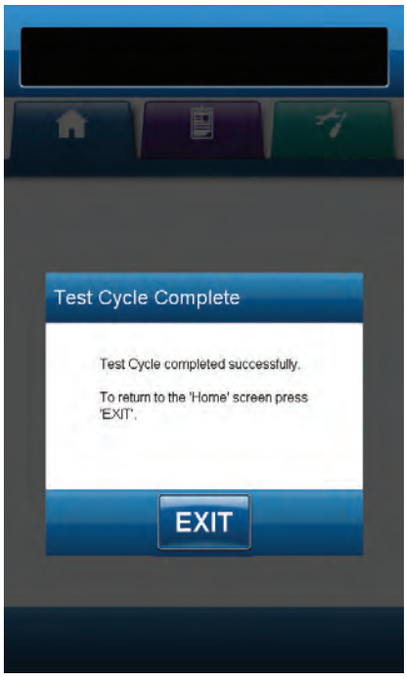
16. Select **OK** to confirm the determined fluid volume as displayed on the ***Fill Assist*** screen and return to the ***Home*** screen (pg. 39 or 45). The therapy unit will then begin the soak phase.

If OK is not selected within 15 minutes of starting Fill Assist or within 15 minutes of stopping Fill Assist, the V.A.C.Ulta™ Therapy Unit will transition to V.A.C.® Therapy phase and the Fill Assist volume will not be recorded.

17. If wound has been over-filled, solution needs to be removed, or Fill Assist needs to be restarted, select **Reset** to remove solution from the wound and return to the ***Fill Assist*** screen.

Test Cycle

Use to complete an abbreviated V.A.C. VeraFlo™ Therapy cycle. Each phase of the cycle will be tested to ensure system is set up and functioning correctly.



1. Ensure that both the V.A.C.® Therapy tube and Instillation tube are properly connected.
2. Ensure that all four tubing clamps are open.
3. Ensure the V.A.C. VeraLink™ Cassette is properly installed (pg. 22).
4. Ensure that the exudate canister is properly installed (pg. 25).
5. Ensure solution bag / bottle is properly installed (pg. 23).
6. If unit has never been configured for V.A.C. VeraFlo™ Therapy, configure unit as described in the V.A.C. VeraFlo™ Therapy Configuration - Overview section (pg. 35 - 38).

Test Cycle is only available while configured for V.A.C. VeraFlo™ Therapy.

If the user does not select any therapy settings, the V.A.C.Ulta™ Therapy Unit will default to factory settings.

7. Select **Test Cycle** from ***Home*** screen (pg. 39 or 45).

8. Once Test Cycle is complete, select **EXIT** to go to V.A.C.® Therapy phase.

Seal Check™ Leak Detector Overview

The Seal Check™ Leak Detector is used to help find negative pressure leaks.

Access the Seal Check™ Leak Detector from the ***Home*** screen. The Seal Check™ Leak Detector will also automatically run during the initial Drawdown phase of V.A.C. VeraFlo™ Therapy and once V.A.C.® Therapy has been initiated.

Most leaks occur:

- where the drape meets the skin.
- where the V.A.C. VeraT.R.A.C.™ Pad, V.A.C. VeraT.R.A.C. Duo™ Tube Set pads or SensaT.R.A.C.™ Pad is attached to the drape.
- at tubing connections.
- if exudate canister is not fully seated to therapy unit.

Seal Check™ Leak Detector

1. Ensure that both the V.A.C.® Therapy tube and Instillation tube are properly connected as applicable.

2. Ensure that all four tubing clamps are open.

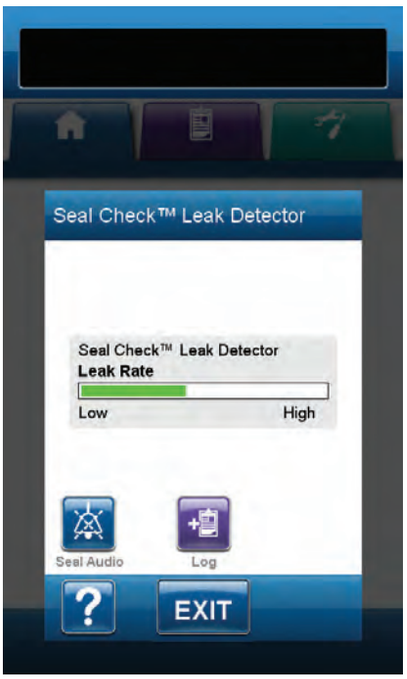
3. Ensure the V.A.C. VeraLink™ Cassette is properly installed (pg. 22), if applicable.

4. Ensure that the exudate canister is properly installed (pg. 25).

5. Select and configure the prescribed therapy settings (**V.A.C. VeraFlo™ Therapy** (pg. 39) or **V.A.C.® Therapy** (pg. 45) by selecting **Therapy Settings**.

6. Once therapy has been initiated, select **Seal Check™** Leak Detector.

The Seal Check™ Leak Detector uses an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and length of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in length as the leak is found.



The bar graph will be yellow if a significant leak is detected. A green bar graph indicates the V.A.C.Ulta™ Therapy Unit is operating normally. The line on the bar graph is the transition point from yellow to green.

During initial dressing draw down, the bar graph should turn yellow and then return to a green state if there are no significant leaks.

7. Select **Seal Audio** to turn seal audio tone on or off.

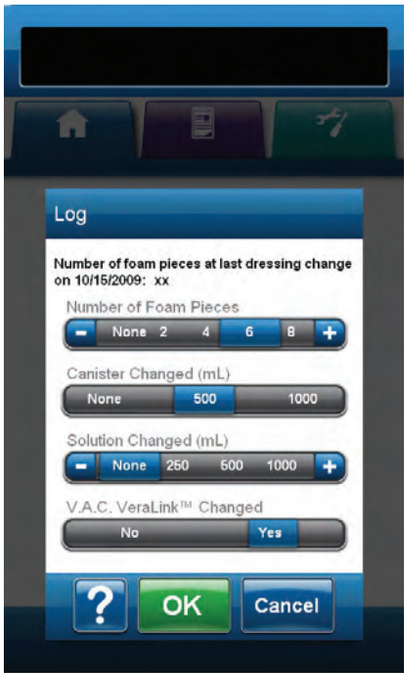
8. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and SensaT.R.A.C.™ or V.A.C. VeraT.R.A.C.™ Pad or V.A.C. VeraT.R.A.C. Duo™ Tube Set pads. The bar graph will decrease and change from yellow to green and the frequency of the audible tone (if Seal Audio is on) will decrease when a leak is found and repaired.

9. Refer to the instructions for use provided with the V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal any leak areas.

10. Select **Exit** to return to the ***Home*** screen.

Log

Use this tool to record important information about dressing and component application / changes. The information will be recorded in the Therapy History Report (pg. 74).



Number of Foam Pieces - Select the number of foam pieces used in the wound at dressing application or dressing change. Use **+** / **-** , as applicable to adjust above or below the values shown.

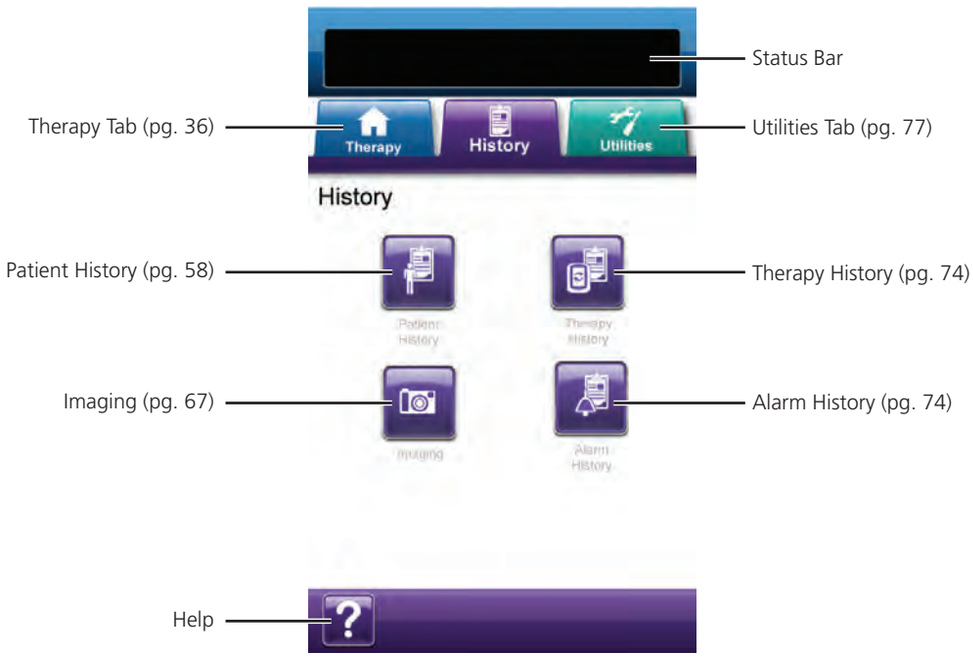
Canister Changed (mL) - Select which canister (500 mL or 1000 mL) was installed or changed.

Solution Changed (mL) - Select the size (100 to 1000) of solution bag / bottle that was installed. Use **+** / **-** , as applicable to adjust above or below the values shown.

V.A.C. VeraLink™ Changed - Select Yes or No to indicate whether or not a V.A.C. VeraLink™ Cassette was installed or changed.

History Tab Screen

Use the ***History Tab*** screen to access History (Patient, Therapy and Alarm) and the Wound Imaging Tool.



The following options are available from the ***History Tab*** screen:

Patient History - The Patient History screen displays the patient's information in date, time and event columns. The date is in ascending order and time is displayed using the twenty-four hour clock format.

Imaging - The Wound Imaging feature aids in recording the wound healing process. Use to upload digital wound images for on-screen viewing or surface area and volume trending.

Therapy History - The Therapy History screen displays the patient's therapy information in date, time and event columns. The date is in ascending order and time is displayed using the twenty-four hour clock format.

Alarm History - The Alarm History screen displays the alarm information from the V.A.C.Ulta™ Therapy Unit in date, time and event columns. The date is in ascending order and time is displayed using the twenty-four hour clock format.

Help - Use to access the V.A.C.Ulta™ Therapy Unit's on-screen help features.

Patient History or Imaging Configuration (First Time Use) - Overview

The following flow charts show the basic steps required to establish an access code and start a new a patient history log. Refer to the following pages for more detailed information about individual screens and options.

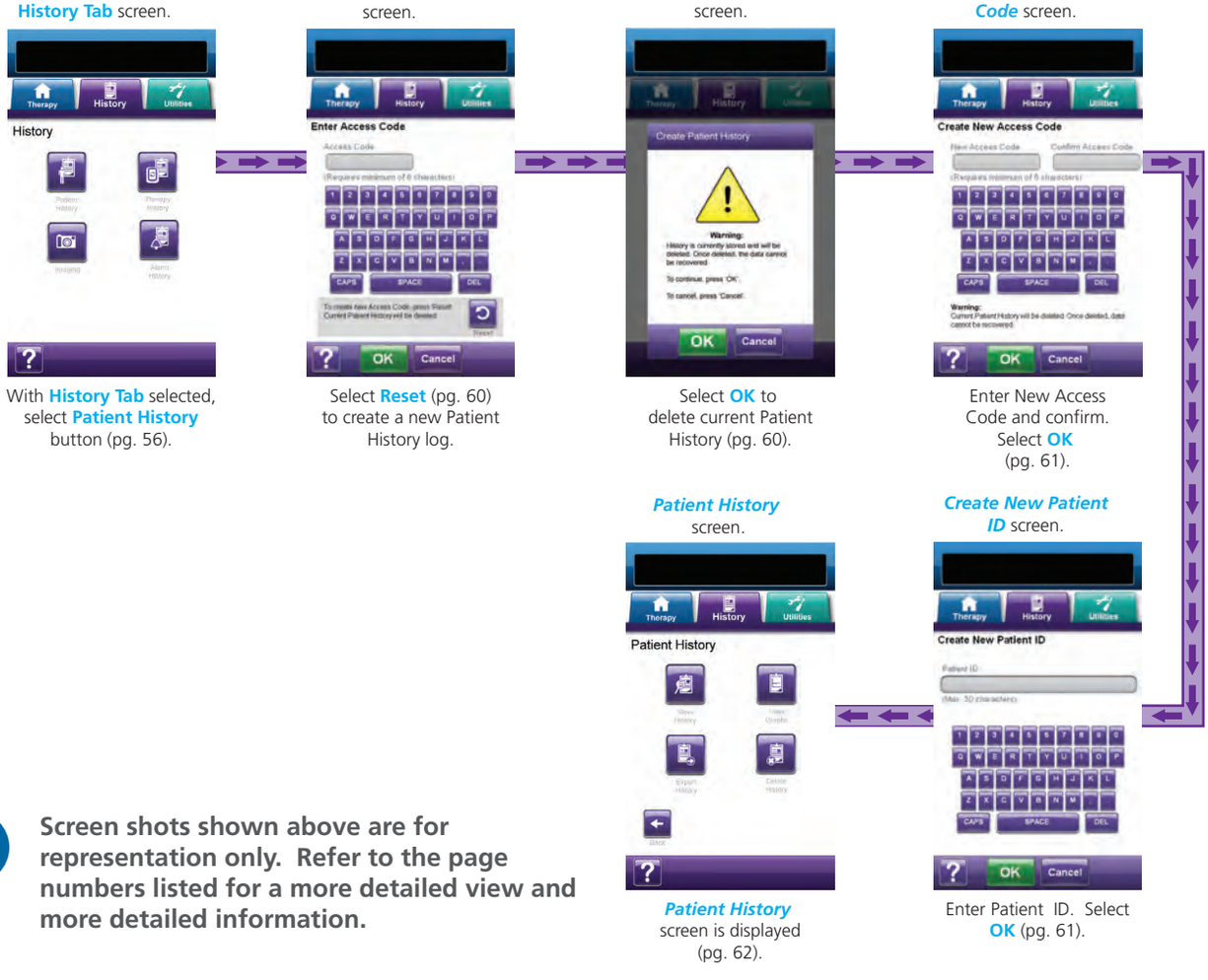
History Tab screen.
With **History Tab** selected, select **Patient History** (pg. 56).

Create New Access Code screen.
Enter New Access Code and confirm. Select **OK** (pg. 58).

Create New Patient ID screen.
Enter Patient ID. Select **OK** (pg. 58).

Patient History screen.
Patient History screen is displayed (pg. 62).

Patient History or Imaging Configuration (New Access Code) - Overview



History Tab screen.
With **History Tab** selected, select **Patient History** button (pg. 56).

Enter Access Code screen.
Select **Reset** (pg. 60) to create a new Patient History log.

Create Patient History screen.
Select **OK** to delete current Patient History (pg. 60).

Create New Access Code screen.
Enter New Access Code and confirm. Select **OK** (pg. 61).

Create New Patient ID screen.
Enter Patient ID. Select **OK** (pg. 61).

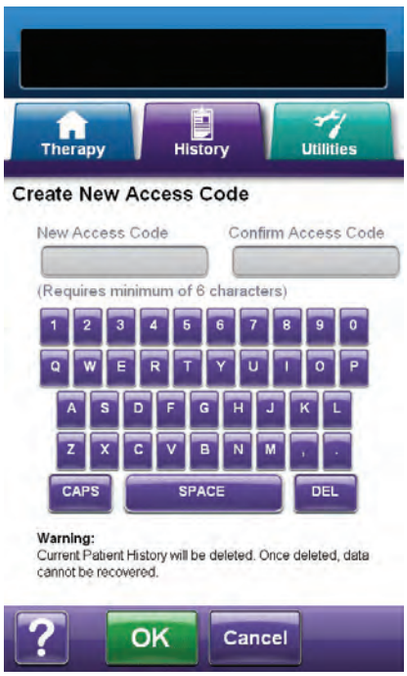
Patient History screen.
Patient History screen is displayed (pg. 62).

Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.

Patient History

Use the Patient History screens to create a new access code and start a new patient history log, view patient history, delete patient history, export patient history, and view a wound image area graph.

Create New Patient History


Therapy
History
Utilities
Create New Access Code
New Access Code
Confirm Access Code
(Requires minimum of 6 characters)
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M , .
CAPS
SPACE
DEL
Warning:
Current Patient History will be deleted. Once deleted, data cannot be recovered.
OK
Cancel

1. Select the **History** tab (pg. 56).

2. Select **Patient History** from the ***History Tab*** screen (pg. 56) to continue to the ***Create New Access Code*** screen.

3. Select the **New Access Code** field and use the on-screen keyboard to enter an access code. The access code must be at least six characters long.

Record the access code. It will be needed each time patient history is accessed.

4. Select the **Confirm Access Code** field and re-enter the access code entered in the **New Access Code** field.

OK

5. Select **OK** to continue to the ***Create New Patient ID*** screen.

6. Select the **Patient ID** field and use the on-screen keyboard to enter the patient's identification (ID). The patient's ID must be less than 30 characters.

OK

7. Select **OK** to continue to the ***Patient History*** screen (pg. 62).

For security purposes, the V.A.C.Ulta™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.

All information will be automatically deleted when the unit is returned to KCI.

Access Patient History

Once an access code is created, it must be entered to access Patient History.

1. Select the **History** tab (pg. 56).

2. Select **Patient History** from the ***History Tab*** screen (pg. 56) to continue to the ***Enter Access Code*** screen.

3. Select the **Access Code** field and use the on-screen keyboard to enter the Patient History access code.

4. Select **OK** to continue to the ***Patient History*** screen (pg. 62).

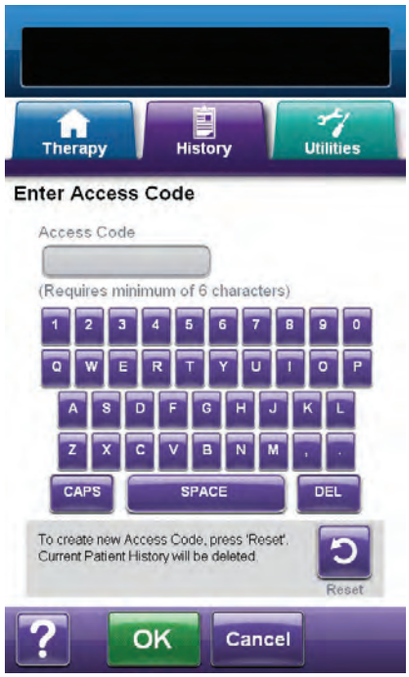
For security purposes, the V.A.C.Ulta™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.

All information will be automatically deleted when the unit is returned to KCI.

For security purposes, if an incorrect access code is entered 12 times, the system will lock. If this happens, contact KCI.

Create New Access Code

In order to create a second patient history log, a new access code must be created. When a second access code is created, all previously recorded patient history will be deleted.



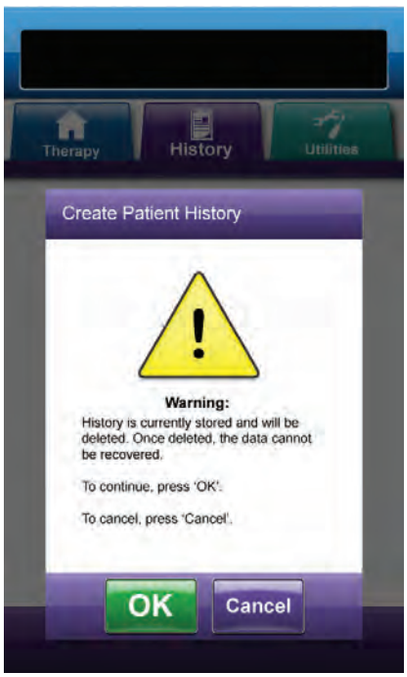
1. Select the **History** tab (pg. 56).

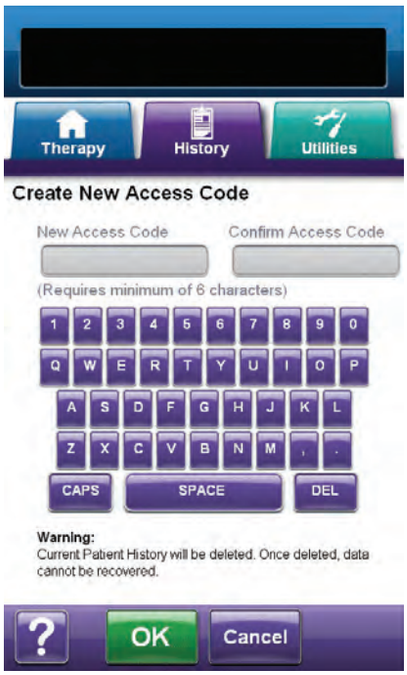
2. Select **Patient History** from the ***History Tab*** screen (pg. 56) to continue to the ***Enter Access Code*** screen.

3. Select **Reset** to create a new access code.

For security purposes, the V.A.C.Ulta™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.

4. Select **OK** on the ***Create Patient History*** warning screen to continue to the ***Create New Access Code*** screen and delete the currently stored history.




Therapy
History
Utilities
Create New Access Code
New Access Code
Confirm Access Code
(Requires minimum of 6 characters)
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M , .
CAPS
SPACE
DEL
Warning:
Current Patient History will be deleted. Once deleted, data cannot be recovered.
OK
Cancel

5. Select the **New Access Code** field and use the on-screen keyboard to enter an access code. The access code must be at least six characters long.

Record the access code. It will be needed each time patient history is accessed.

6. Select the **Confirm Access Code** field and re-enter the access code entered in the **New Access Code** field.

OK

7. Select **OK** to continue to the ***Create New Patient ID*** screen.

8. Select the **Patient ID** field and use the on-screen keyboard to enter the patient's identification (ID). The patient's ID must be 30 characters or less.

OK

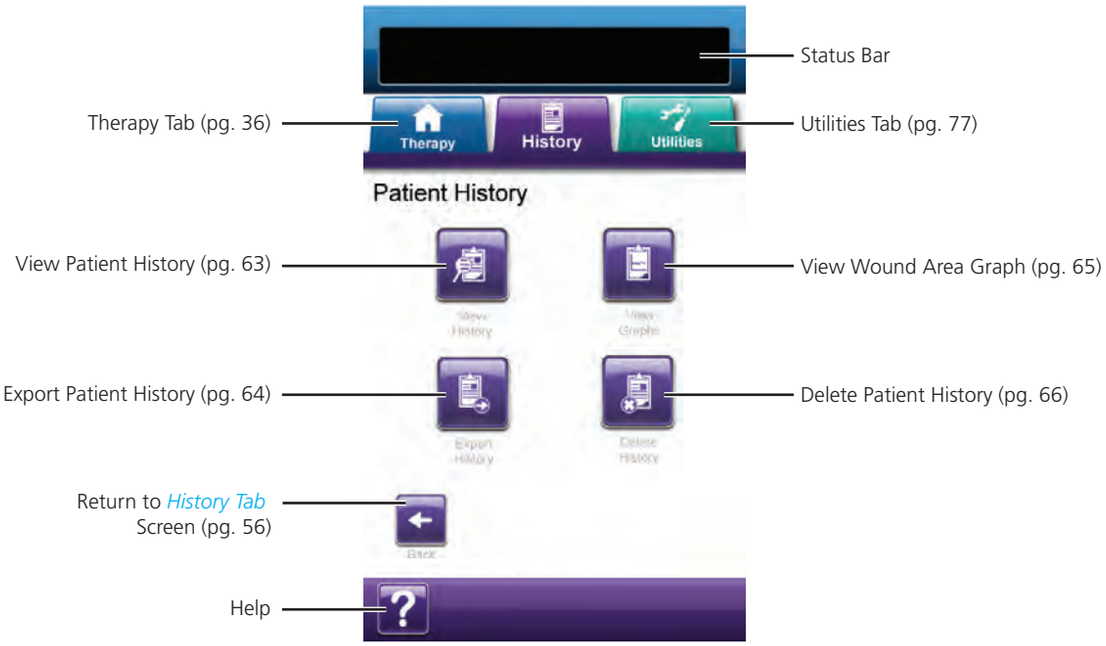
9. Select **OK** to continue to the ***Patient History*** screen (pg. 62).

For security purposes, the V.A.C.Ulta™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.

All information will be automatically deleted when the unit is returned to KCI.

Patient History Screen

Use the Patient History Screen to view, export, or delete a Patient History log (e.g. wound imaging information and disposable component changes).



The following options are available from the ***Patient History*** screen:

View History - Use to view patient history and add short notes about the patient's treatment. For a new patient history log, this screen will not have any event entries.

Export History - Use to export all patient history to a USB Drive or SD Card.

View Graph - Use to view a graph of the measured wound area over time.

Delete History - Use to delete the patient history data from the V.A.C.Ulta™ Therapy unit's memory.

View Patient History Screen

Use the ***View Patient History*** screen to view and add short notes about the patient's treatment. For a new patient history log, this screen will not have any event entries.

1. Select **View History** from the ***Patient History*** screen (pg. 62) to continue to the ***View Patient History*** screen.

2. Use the **Up** and **Down** arrows to scroll through the patient's history.

3. Select **Add Note** to continue to the ***Add Note*** screen.

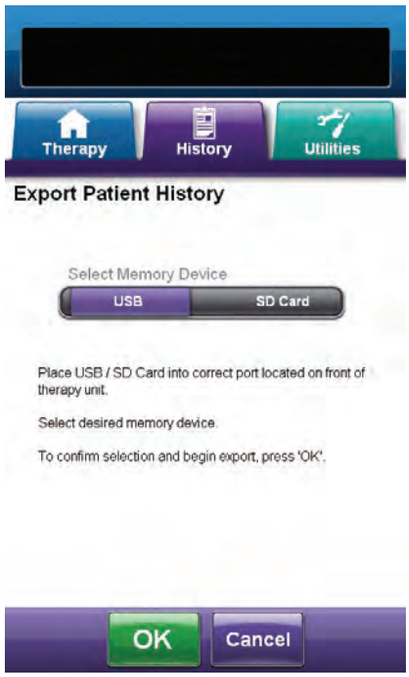
4. Use the on-screen keyboard to add notes about the patient's history. The note must be less than 30 characters.

5. Select **OK** to add the note, or **Cancel** to return to the ***View Patient History*** screen without adding the note.

6. Select **Back** to return to the ***Patient History*** Home screen.

Export Patient History Screen

Use the ***Export Patient History*** screen to export patient history to a USB Drive or SD Card.



1. Select **Export History** from the ***Patient History*** screen (pg. 62) to continue to the ***Export Patient History*** screen.

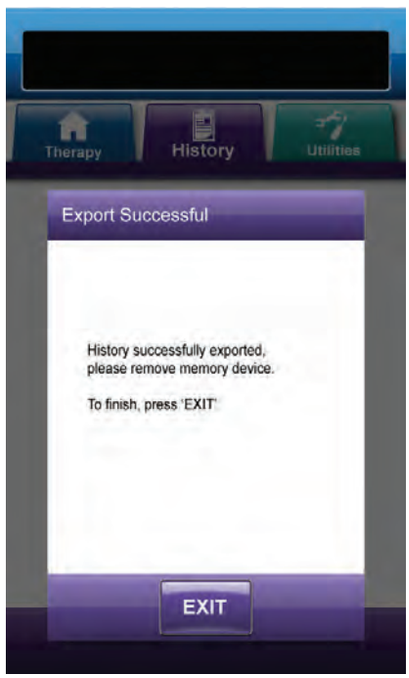
2. Insert the desired memory device (USB Drive or SD Card) into the proper port on the front of the V.A.C.Ulta™ Therapy Unit (pg. 14).

3. On the ***Export Patient History*** screen, select the memory device being used, **USB** or **SD Card**.

4. Select **OK** to begin exporting patient history to the memory device or select **Cancel** to return to the ***Patient History*** screen without exporting patient history.

5. The V.A.C.Ulta™ Therapy Unit will begin exporting patient history. A bar graph will display transfer progress.

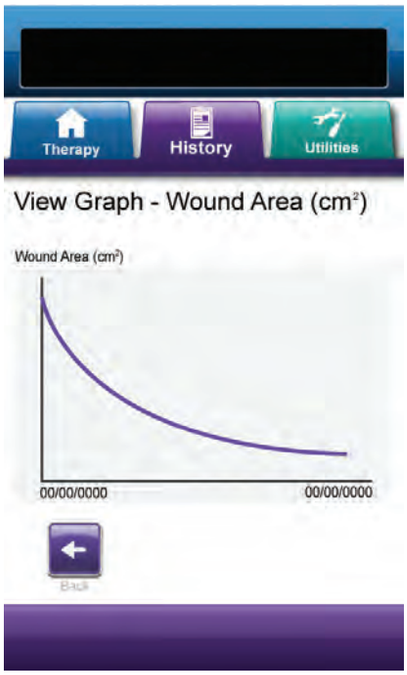
If the V.A.C.Ulta™ Therapy Unit detects an error during transfer, the Export Transfer Error screen will appear. Refer to the Data Transfer Errors section (pg. 76) of this manual for information about resolving this error.



6. Once all patient history is successfully transferred to the memory device, select **Exit** on the ***Export Successful*** screen to return to the ***Patient History*** screen.

View Graph - Wound Area (cm^2) Screen

Use the ***View Graph - Wound Area (cm^2)*** screen to view a graph of the measured wound area over time.



1. Select **View Graph** from the ***Patient History*** screen (pg. 62) to continue to the ***View Graph - Wound Area (cm^2)*** screen.

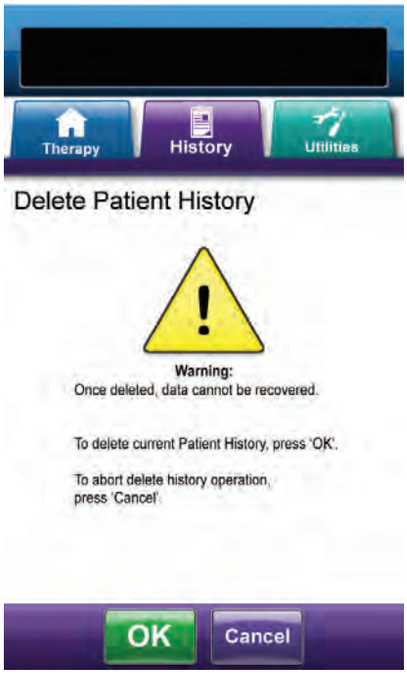
A graph cannot be constructed if the patient history file has been deleted.

A graph cannot be constructed unless measurements of the wound area have been previously saved in the patient's history. At least two measurements from different days are required (area of the image against time) for a graph to be constructed. Refer to the Wound Imaging section (pg. 67) of this manual for complete details about entering this information in the patient's history.

2. Select **Back** to return to the ***Patient History*** screen.

Delete Patient History Screen

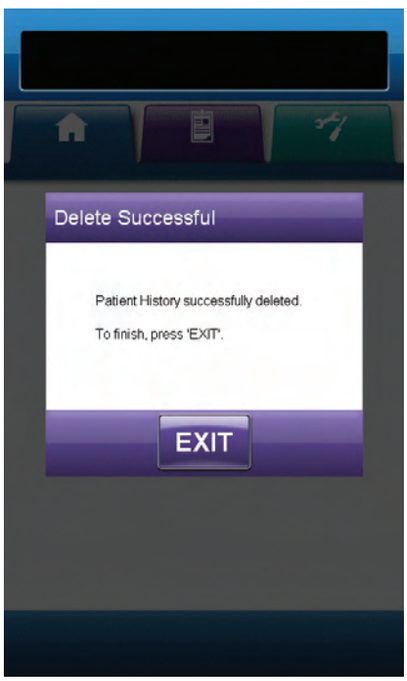
Use the ***Delete Patient History*** screen to delete patient history data from the V.A.C.Ulta™ Therapy Unit's memory.



1. Select **Delete History** from the ***Patient History*** screen (pg. 62) to continue to the ***Delete Patient History*** warning screen.

2. Select **OK** to confirm deletion or **Cancel** to return to the ***Patient History*** screen without deleting patient history.

3. Once the deletion is complete, select **Exit** on the ***Delete Successful*** screen to return to the ***Patient History*** screen.



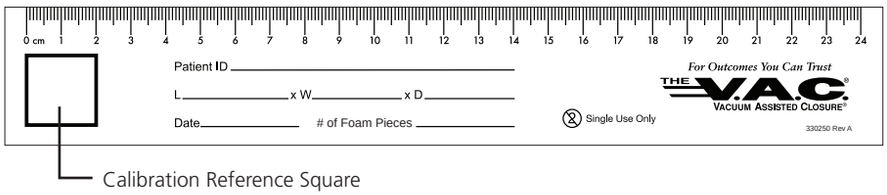
Wound Imaging

Use the Wound Imaging feature to aid in recording the wound healing process.

Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.

Accessories required to use this feature include:

- Digital camera with at least two megapixel resolution and that uses an SD Memory Card
- An SD Memory Card
- Calibration Reference Square - located on the ruler in the dressing kit. This reference square is needed for the V.A.C.Ulta™ Therapy Unit to calculate wound measurements.


0 cm 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Patient ID
L x W x D
Date # of Foam Pieces
Single Use Only
For Outcomes You Can Trust
THE V.A.C.
VACUUM ASSISTED CLOSURE
330250 Rev A
Calibration Reference Square

- Stylus - located inside the door on the front of the V.A.C.Ulta™ Therapy Unit (pg. 14).

The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.

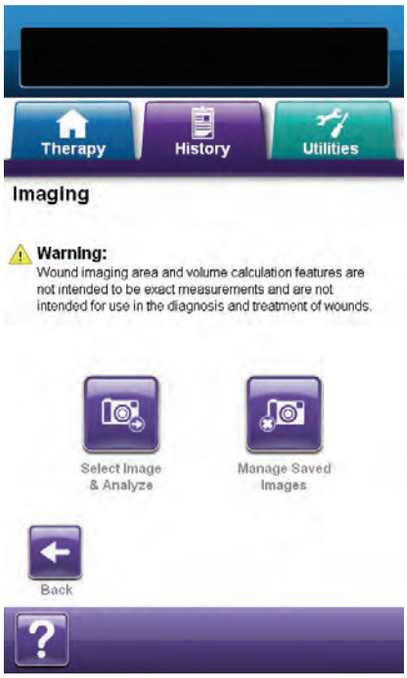
For optimal operation of the Wound Imaging feature, it is recommended that:

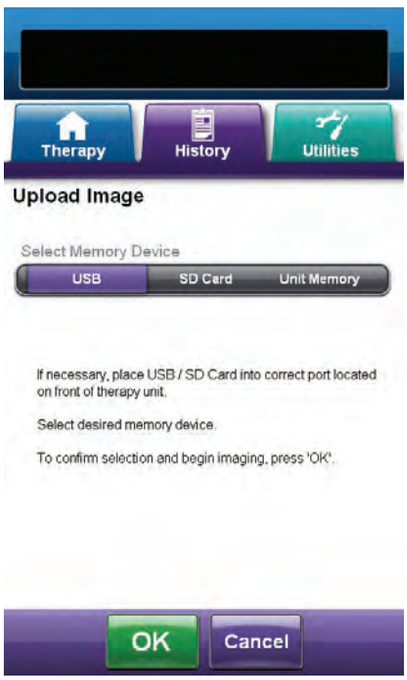
- The sterile Calibration Reference Square be placed in the same location on the wound each time an image is taken.
- All images be taken directly above the wound.
- The wound and Calibration Reference Square fill as much of the image as possible.
- The image be taken in good lighting conditions.
- Image files must be taken directly from the camera's SD Memory card.

Using a camera that has a date and time function will allow for easier tracking of images.

Imaging Screen

Use the ***Imaging*** screen to upload images for calculating wound area and volume and to delete images from the V.A.C.Ulta™ Therapy Unit.


Therapy
History
Utilities
Imaging
Warning:
Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.
Select Image & Analyze
Manage Saved Images
Back



Uploading Images

1. From the ***History Tab*** screen (pg. 56), select **Imaging** to continue to the ***Imaging*** screen.

2. Enter Patient History access code (pg. 59).

A Patient History Log must be created prior to using the Imaging feature. Refer to the Create New Patient History section (pg. 58) of this manual for more information.

3. Insert memory device into the proper slot on front of the V.A.C.Ulta™ Therapy Unit (pg. 14)

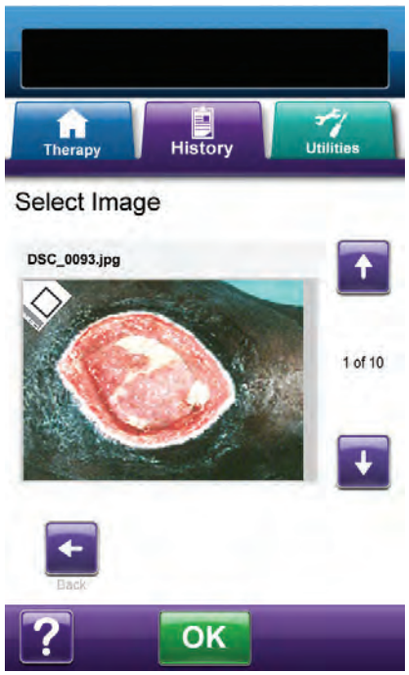
4. Select **Select Image & Analyze** to continue to the ***Upload Image*** screen.

5. Select the memory device that contains the images from the ***Upload Images*** screen. Select **USB**, **SD Card**, or **Unit Memory**.

There will be short delay while the images are accessed from the V.A.C.Ulta™ Therapy Unit's memory or the memory card.

When selecting unit memory, the Select Image screen will be blank unless images have been previously uploaded and saved in unit memory.

6. Select **OK** to continue to the ***Select Image*** screen. Select **Cancel** to return to the ***Imaging*** screen.



7. Use the **Up** and **Down** arrows to display the desired image in the window.

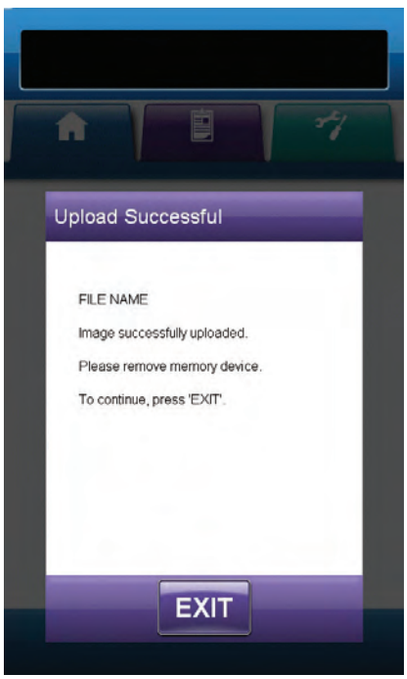
8. When the desired image is displayed, select **OK** to load the image into the V.A.C.Ulta™ Therapy Unit's memory.

9. The V.A.C.Ulta™ Therapy Unit will begin uploading the image. A bar graph will display transfer progress.

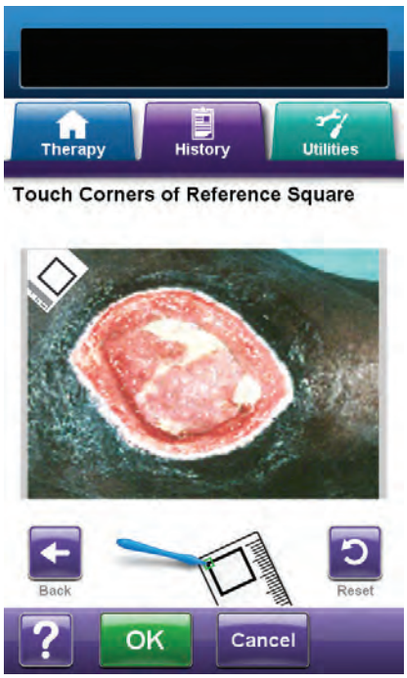
If the V.A.C.Ulta™ Therapy Unit detects an error during transfer, the *Upload Transfer Error* screen will appear. Refer to the Data Transfer Errors section (pg. 76) of this manual for information about resolving this error.

10. Once image is successfully transferred, remove the memory device.

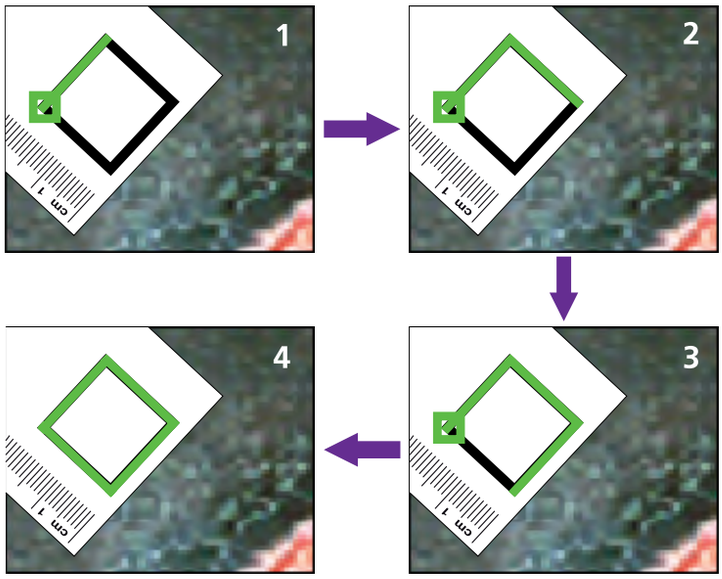
11. Select **Exit** on the ***Upload Successful*** screen to continue to the ***Touch Corners of Reference Square*** screen.



Analyzing Images - Touch Corners of Reference Square



12. Use the supplied stylus to touch each corner of the reference square displayed in the image window on the ***Touch Corners of Reference Square*** screen.



When the last corner of the reference square is touched, the corner points will be joined by a highlighted line.

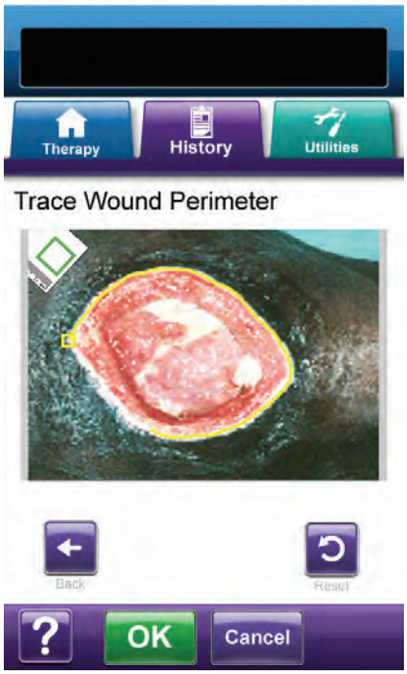
The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.

A square will appear at the start of the trace. The trace is completed when the end of the line returns to the start point.

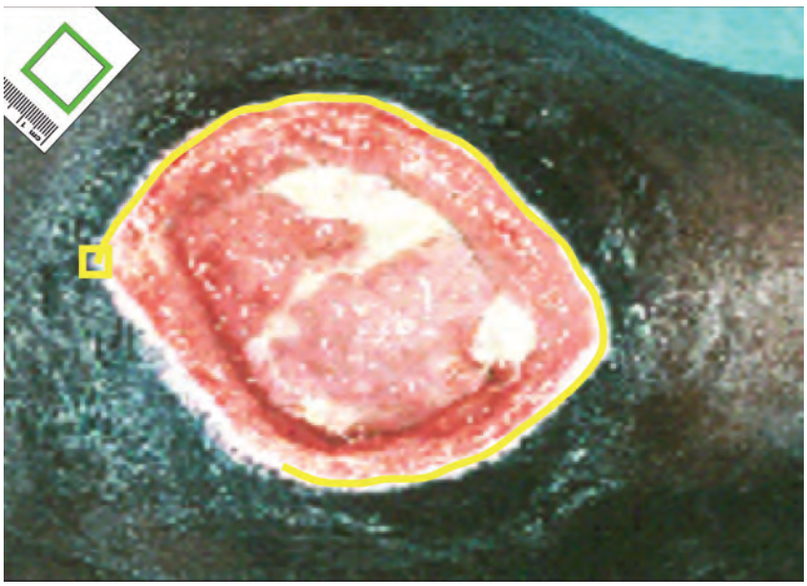
It is important to select corners in either a clockwise or counter-clockwise manner. Incorrect sequence will lead to a calibration error.

13. Once the reference square has been traced, select **OK** to continue to the ***Trace Wound Perimeter*** screen.

Analyzing Images - Trace Wound Perimeter



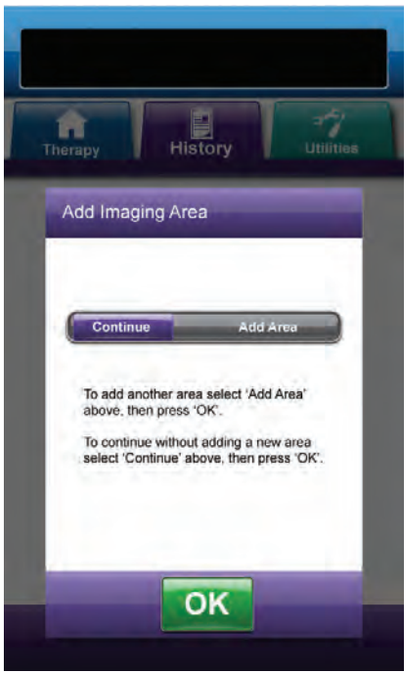
14. Use the supplied stylus to trace a line around the wound area to be analyzed in the image window on the ***Trace Wound Perimeter*** screen.



If an error is made during tracing, select **Reset** to trace the wound area again.

The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.

A square will appear at the start of the trace. The trace is completed when the end of the line returns to the start point.



OK

15. Once the wound area has been traced, select **OK** to continue to the ***Add Imaging Area*** screen.

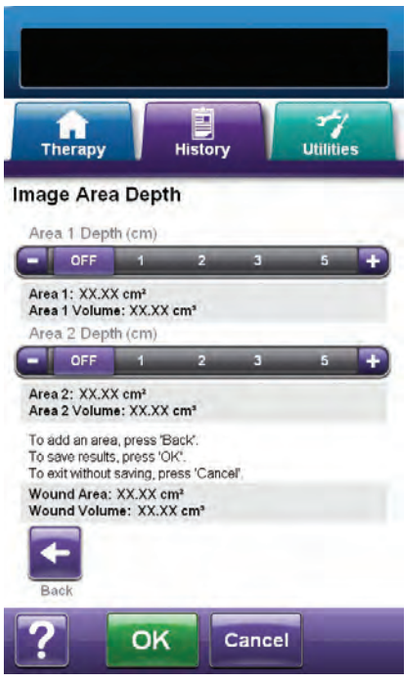
16. Select **Add Area** to continue back to the ***Trace Wound Perimeter*** screen if there is an additional wound area to be traced.

17. Select **Continue** if all wound area(s) have been traced.

OK

18. Select **OK** to continue to the ***Image Area Depth*** screen.

Analyzing Images - Image Area Depth



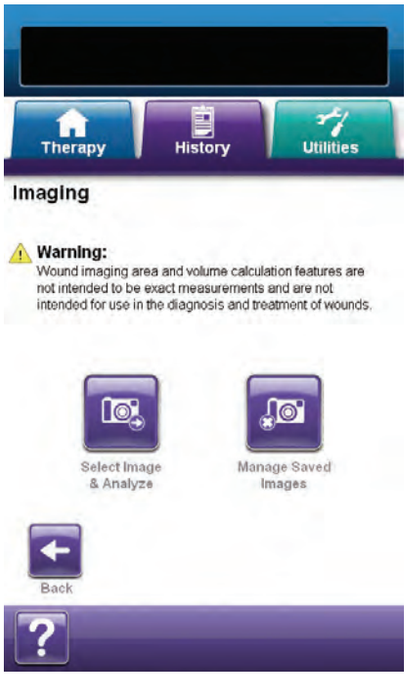
19. Select the approximate depth of each wound area traced. Use **+** / **-**, as applicable to adjust above and below values shown.

20. Select **Back** to return to the ***Add Imaging Area*** screen.

21. Select **OK** to save wound imaging data to the patient's history.

22. Select **Cancel** to return to the ***Upload Image*** screen.

Delete Images


Therapy
History
Utilities
Imaging
Warning:
Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.
Select Image & Analyze
Manage Saved Images
Back

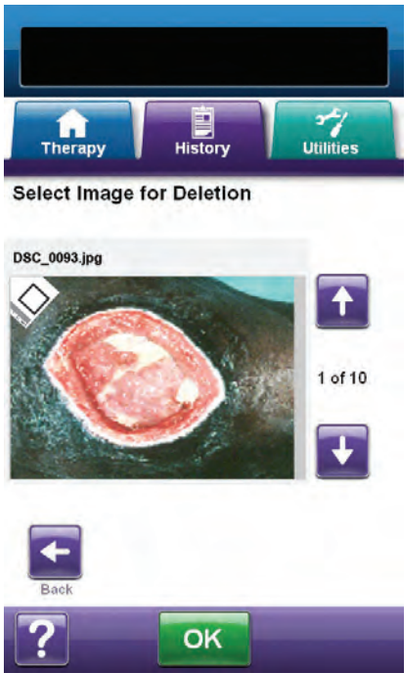
1. From the ***History Tab*** screen (pg. 56), select **Imaging** to continue to the ***Imaging*** screen.

2. Enter Patient History access code.

A Patient History Log must be created prior to using the Imaging feature. Refer to the Create New Patient History section (pg. 58) of this manual for more information.

3. Select **Manage Saved Images** to continue to the ***Select Image for Deletion*** screen.

There will be short delay while the images are accessed from the V.A.C.Ulta™ Therapy Unit's memory.



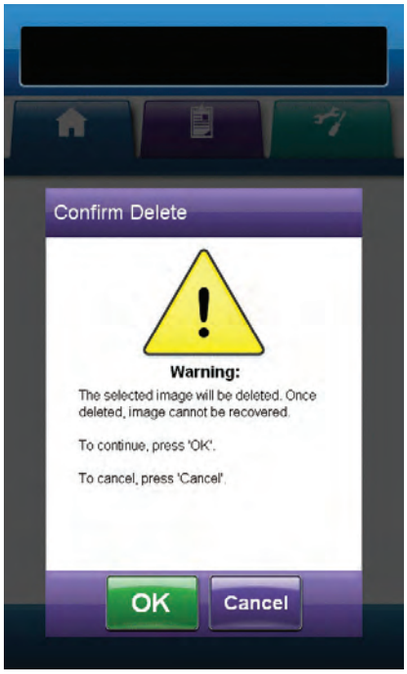
4. Use the **Up** and **Down** arrows to display the desired image in the window.

5. When the desired image is displayed, select **OK** to continue to the ***Confirm Delete*** screen.

6. Select **OK** to delete the image from the V.A.C.Ulta™ Therapy Unit's memory or select **Cancel** to return to the ***Select Image for Deletion*** screen.

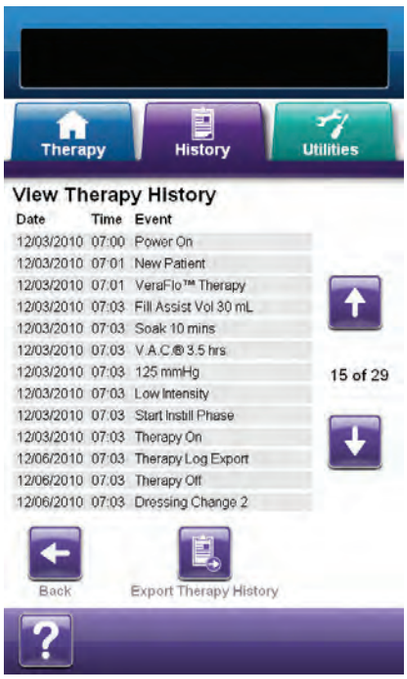
7. Once the image is successfully deleted, the ***Select Image for Deletion*** screen will be displayed. Select another image to delete, or select **Back** to return to the ***Imaging*** screen.

8. Select the **History** Tab to return to the ***History Tab*** screen.



Therapy History Screen

The ***View Therapy History*** screen displays the patient's therapy information in date, time and event columns (e.g. therapy starts / stops, therapy settings and disposable component changes). The date is in ascending order and time is displayed using the twenty-four hour clock format.



1. From the ***History Tab*** screen (pg. 56), select **Therapy History** to continue to the ***View Therapy History*** screen.

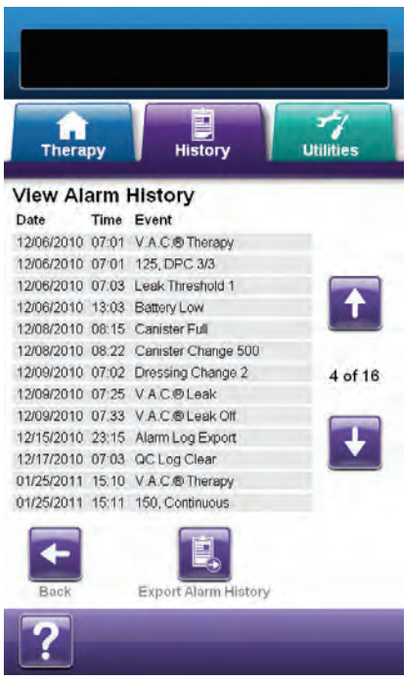
2. Use the **Up** and **Down** arrows to scroll through the therapy history.

3. Select **Back** to return to the ***History Tab*** screen.

4. Select **Export Therapy History** to continue to the ***Export History*** screen (pg. 75).

Alarm History Screen

The ***View Alarm History*** screen displays alarm information for the V.A.C.Ulta™ Therapy Unit in date, time and event columns (e.g. alarms and disposable component changes). The date is in ascending order and time is displayed using the twenty-four hour clock format.



1. From the ***History Tab*** screen (pg. 56), select **Alarm History** to continue to the ***View Alarm History*** screen.

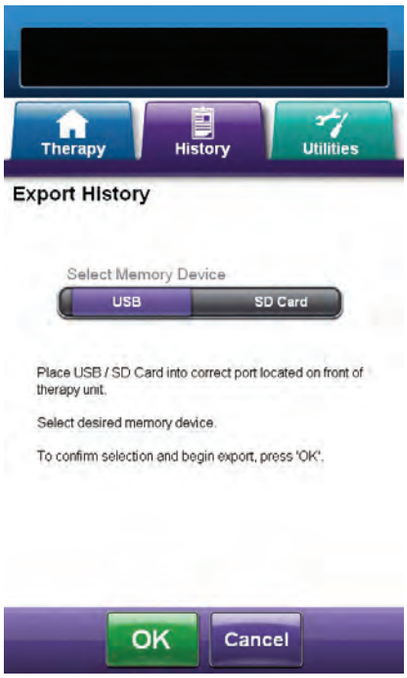
2. Use the **Up** and **Down** arrows to scroll through the alarm history.

3. Select **Back** to return to the ***History Tab*** screen.

4. Select **Export Alarm History** to continue to the ***Export History*** screen (pg. 75).

Export History Screen

Use the ***Export History*** screen to export therapy and alarm history to a memory device (USB or SD Card).



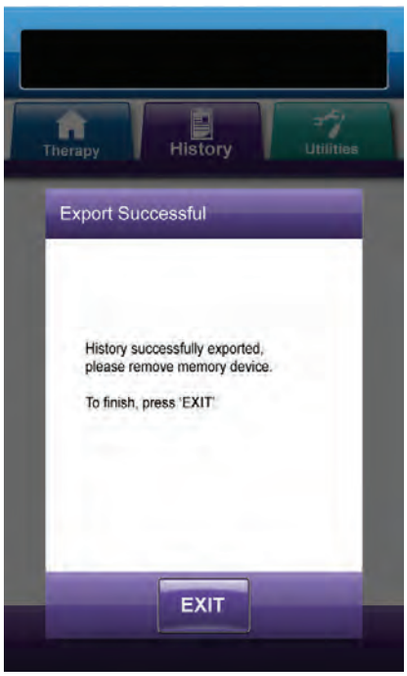
1. Insert the desired memory device (USB or SD Card) into the proper port on the front of the V.A.C.Ulta™ Therapy Unit (pg. 14).

2. On the ***Export History*** screen, select the memory device being used, **USB** or **SD Card**.

3. Select **OK** to begin exporting history to the memory device or select **Cancel** to return to the ***View Therapy*** or ***Alarm History*** screen without exporting history.

4. The V.A.C.Ulta™ Therapy Unit will begin exporting history. A bar graph will display transfer progress.

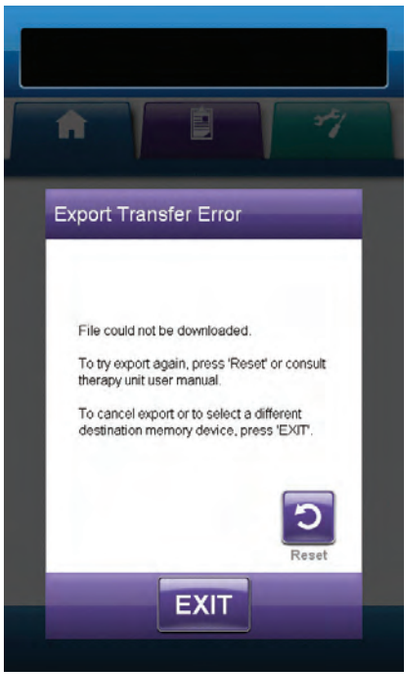
If the V.A.C.Ulta™ Therapy Unit detects an error during transfer, the Export Transfer Error screen will appear. Refer to the Data Transfer Errors section (pg. 76) of this manual for information about resolving this error.



5. Once all history is successfully transferred to the memory device, select **Exit** on the ***Export Successful*** screen to return to the ***History Tab*** screen.

Data Transfer Errors

If the V.A.C.Ulta™ Therapy Unit detects an error during data transfer, the unit will display a Transfer Error screen.

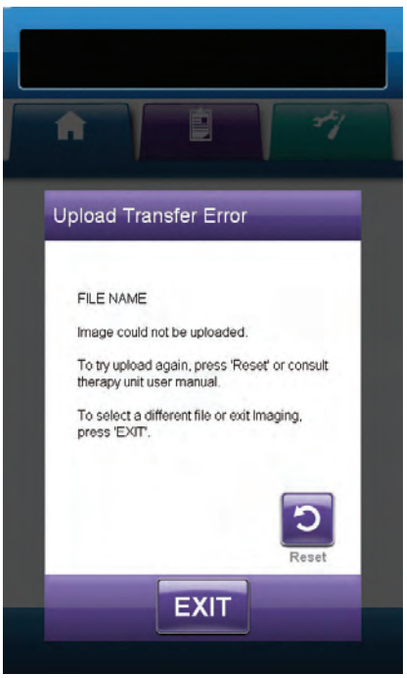

Export Transfer Error
File could not be downloaded.
To try export again, press 'Reset' or consult therapy unit user manual.
To cancel export or to select a different destination memory device, press 'EXIT'.
Reset
EXIT

If the ***Export Transfer Error*** screen appears, the possible reasons for transfer errors are:

- SD Card / USB Drive not inserted properly.
- Incorrect SD card / USB drive format.
- Incorrect type of device connected.

1. Select **Reset** to return to try the export again.

2. Select **Exit** to cancel the export or to select a different destination device.


Upload Transfer Error
FILE NAME
Image could not be uploaded.
To try upload again, press 'Reset' or consult therapy unit user manual.
To select a different file or exit Imaging, press 'EXIT'.
Reset
EXIT

If the ***Upload Transfer Error*** screen appears, the possible reasons for transfer errors are:

- SD Card / USB Drive not inserted properly.
- Incorrect SD card / USB drive format.
- Incorrect type of device connected.
- V.A.C.Ulta™ Therapy Unit's memory is full.

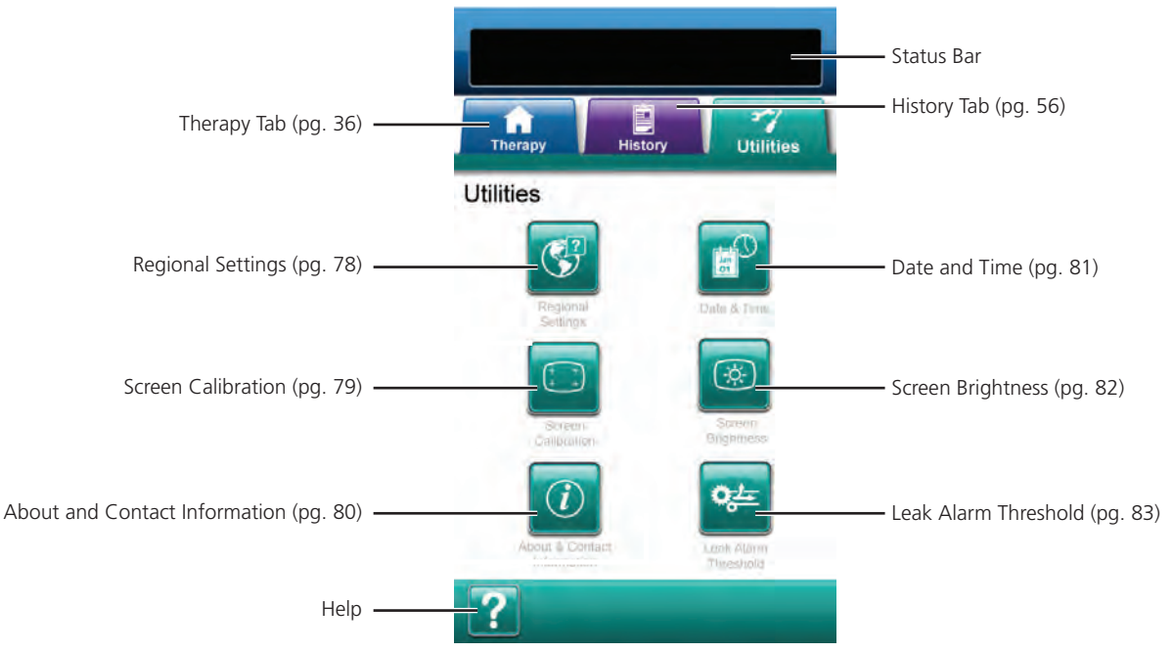
If therapy unit's memory is full, delete any unused photos to free memory. Refer to Delete Images section (pg. 72) for information on deleting images.

1. Select **Reset** to return to try the upload again.

2. Select **Exit** to select a different image (pg. 69) or to exit Imaging.

Utilities Tab Screen

Use the ***Utilities Tab*** screen to set preferences for the V.A.C.Ulta™ Therapy Unit.



The following options are available from the ***Utilities Tab*** Home screen:

Regional Settings - Use to set the language, units of measure, number format and date format displayed by the V.A.C.Ulta™ Therapy Unit.

Screen Calibration - Use to calibrate the V.A.C.Ulta™ Therapy Unit's touch screen.

About and Contact Information - Use to access information about the V.A.C.Ulta™ Therapy Unit, including the software version and KCI contact information.

Date and Time - Use to set the current date and time.

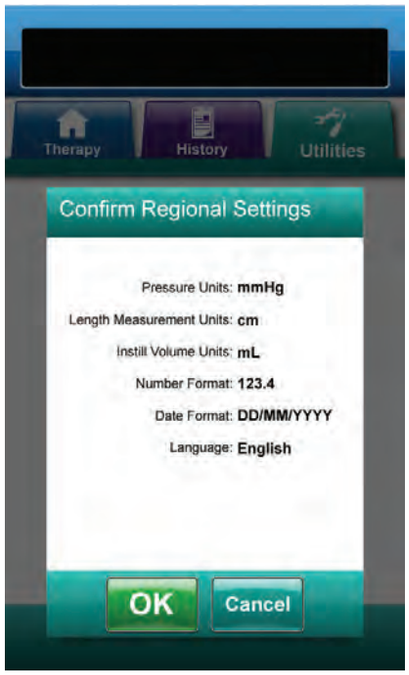
Screen Brightness - Use to adjust the brightness of the V.A.C.Ulta™ Therapy Unit's touch screen.

Leak Alarm Threshold - Use to set the leak rate threshold that triggers the V.A.C.® Therapy Leak Alarm.

Help - Use to access the V.A.C.Ulta™ Therapy Unit's on-screen help features.

Regional Settings Screen

Use the ***Regional Settings*** screen to set the language, unit of measure, number format and date format displayed by the V.A.C.Ulta™ Therapy Unit.



1. Select the **Utilities** tab (pg. 77).

2. Select **Regional Settings** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***Regional Settings*** screen.

3. Set the following options:

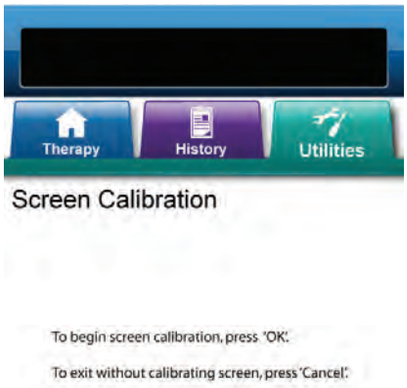
   - **Pressure Units** - Select between **mmHg** (millimeters of mercury) or **kPa** (kilo-Pascals).
   - **Length Units** - Select between **cm** (centimeters) or **inch** (inches).
   - **Instill Volume Units** - Select between **mL** (milliliters) or **cc** (cubic centimeters).
   - **Number Format** - Select decimal separator "." or "," (**123.4** or **123,4**).
   - **Date Format** - Select between **DD/MM/YYYY** or **MM/DD/YYYY**.
   - **Language** - Select the display language for the V.A.C.Ulta™ Therapy Unit.

4. Once all options have been selected, select **OK** to continue to the ***Confirm Regional Settings*** screen. Confirm the selected options.

5. Select **OK** to return to the ***Utilities Tab*** screen. Select **Cancel** to return to the ***Regional Settings*** screen to make any required adjustments.

Screen Calibration Screen

Use the ***Screen Calibration*** screen to calibrate the V.A.C.Ulta™ Therapy Unit's touch screen. If screen inputs are not correctly recognized, it may be necessary to calibrate the touch screen.

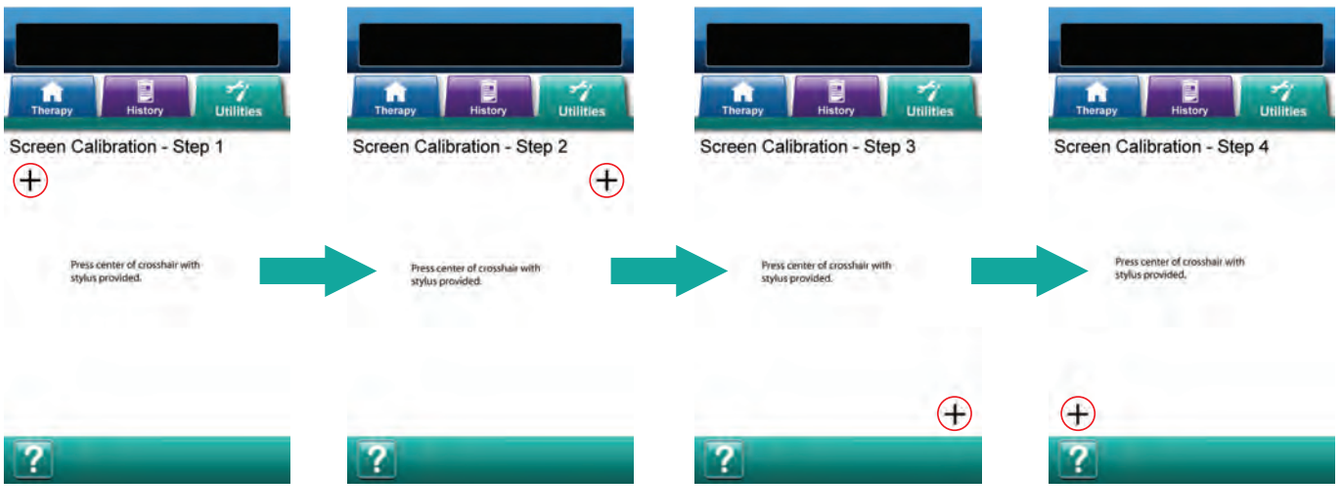


1. Select the **Utilities** tab (pg. 77).

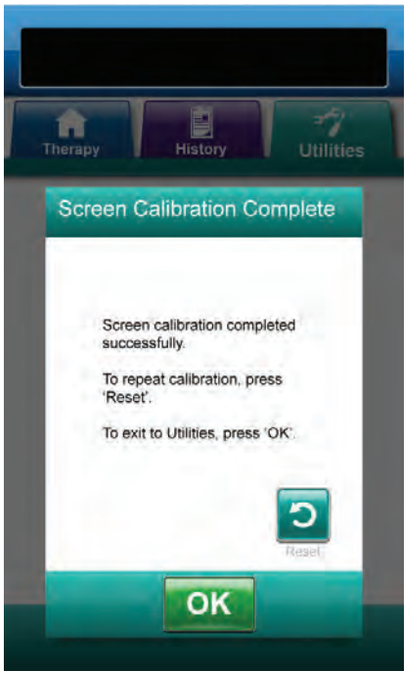
2. Select **Screen Calibration** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***Screen Calibration*** screen.

3. Select **OK** to begin calibrating the touch screen.

4. Using the suppled stylus, touch the center of each cross as it is displayed on the touch screen.



The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.

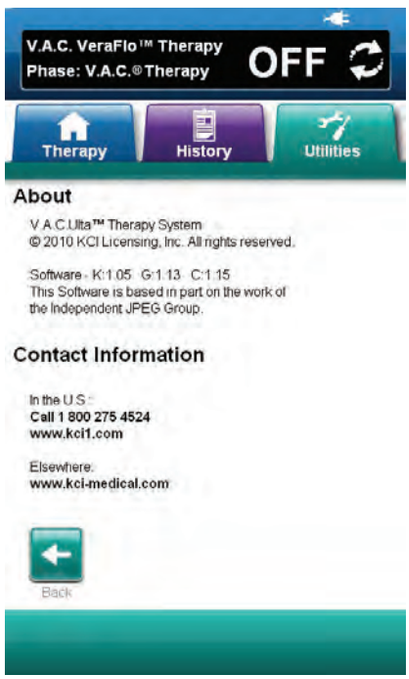


5. Once Step 4 of screen calibration is complete, the ***Screen Calibration Complete*** screen will appear. Select **Reset** on the ***Screen Calibration Complete*** screen to repeat calibration (if necessary).

6. Select **OK** to return to the ***Utilities Tab*** screen.

About and Contact Information Screen

Use the ***About*** and ***Contact Information*** screen to access information about the V.A.C.Ulta™ Therapy Unit, including the software version and KCI contact information.



1. Select the **Utilities** tab (pg. 77).

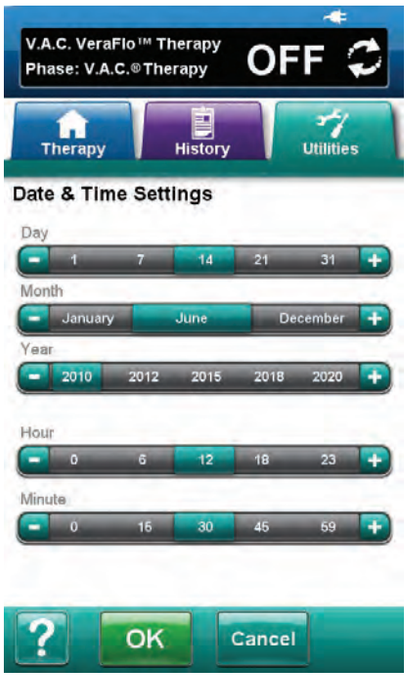
2. Select **About & Contact Information** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***About*** and ***Contact Information*** screen.

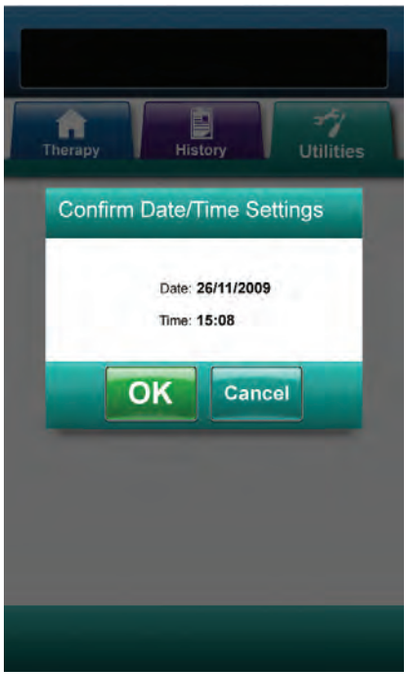
   - About - Shows current software version information
   - Contact Information - Shows KCI contact information

3. Select **Back** to return to the ***Utilities Tab*** screen.

Date & Time Settings Screen

Use the ***Date & Time Settings*** screen to set the current date and time.





1. Select the **Utilities** tab (pg. 77).

2. Select **Date & Time** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***Date & Time Settings*** screen.

3. Set the following options:

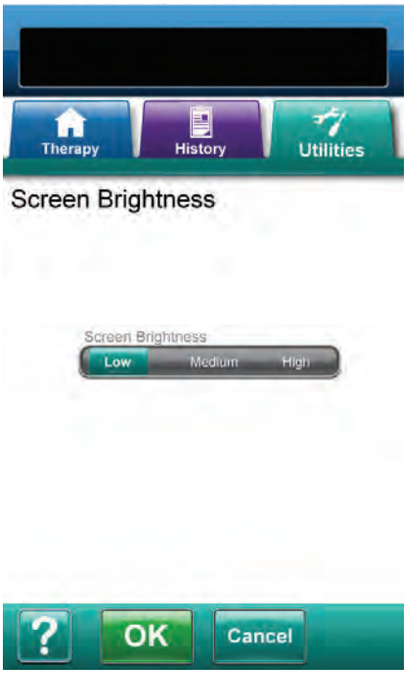
   - **Day** - Select the current day. Use **+** / **-** to adjust above and below values shown.
   - **Month** - Select the current month. Use **+** / **-** to adjust above and below values shown.
   - **Year** - Select the current year. Use **+** / **-** to adjust above and below values shown.
   - **Hour** - Select the current hour of the current time. Use **+** / **-** to adjust above and below values shown.
   - **Minute** - Select the current minute of the current time. Use **+** / **-** to adjust above and below values shown.

4. Once all options have been selected, select **OK** to continue to the ***Confirm Date/Time Settings*** screen. Confirm the selected options.

5. Select **OK** to return to the ***Utilities Tab*** screen. Select **Cancel** to return to the ***Utilities Tab*** screen without making any adjustments to the date and time.

Screen Brightness Screen

Use the ***Screen Brightness*** screen to adjust the brightness of the V.A.C.Ulta™ Therapy Unit's touch screen.



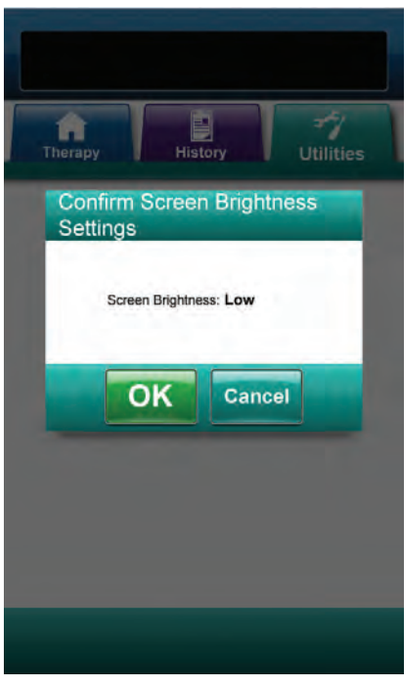
1. Select the **Utilities** tab (pg. 77).

2. Select **Screen Brightness** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***Screen Brightness*** screen.

3. Select the desired screen brightness - **Low**, **Medium**, or **High**.

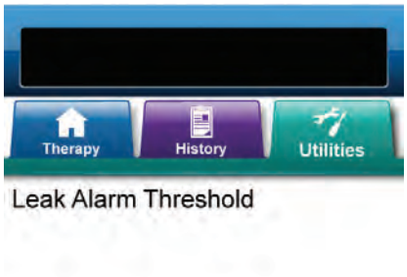
4. Once the desired screen brightness has been selected, select **OK** to continue to the ***Confirm Screen Brightness Settings*** screen. Confirm selected options.

5. Select **OK** to return to the ***Utilities Tab*** screen. Select **Cancel** to return to the ***Utilities Tab*** screen without making any adjustments to the screen brightness.



Leak Alarm Threshold Screen

Use the ***Leak Alarm Threshold*** screen to set the leak rate threshold that triggers the V.A.C.® Therapy Leak Alarm.



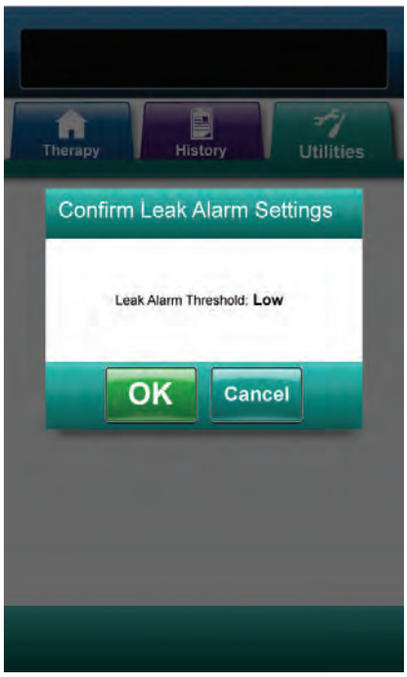
1. Select the **Utilities** tab (pg. 77).

2. Select **Leak Alarm Threshold** from the ***Utilities Tab*** screen (pg. 77) to continue to the ***Leak Alarm Threshold*** screen.

3. Select the desired negative pressure leak alarm threshold. Threshold options are **Low** or **High**. Low is approximately equal to one liter per minute. High is approximately equal to two liters per minute.

4. Once the desired negative pressure leak alarm threshold has been selected, select **OK** to continue to the ***Confirm Leak Alarm Settings*** screen. Confirm selected options.

5. Select **OK** to return to the ***Utilities Tab*** screen. Select **Cancel** to return to the ***Utilities Tab*** screen without making any adjustments to the negative pressure leak alarm threshold.



Alerts and Alarms

Alerts and Alarms appear on the touch screen and are accompanied by a repeating audible tone.

Following initiation of therapy, if an audible tone is not heard when Seal Check™ Leak Detector is displayed, the alarms may not be working properly. Contact KCI for more information. Alarms are intended to be heard when facing the therapy unit at a maximum of one meter away. If two or more alarm conditions are present, only the highest priority alarm will be displayed.

Low Priority Alarm / Alert Condition - Displayed on the touch screen when the V.A.C.Ulta™ Therapy Unit detects a condition that requires attention. Alerts will be accompanied by a repeating audible tone approximately every 20 seconds (two beeps).

Medium Priority Alarm Condition - Displayed on the touch screen when the V.A.C.Ulta™ Therapy Unit detects a condition that requires prompt attention in order to ensure the prescribed therapy is being delivered. Alarms will be accompanied by a repeating audible tone approximately every two seconds (three beeps) and a flashing screen title.

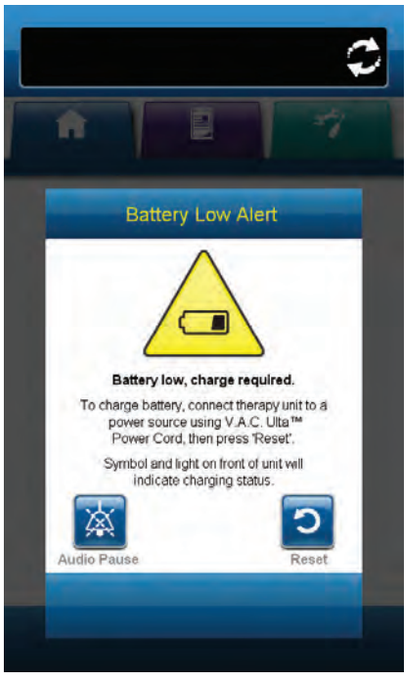
Select **Audio Pause** to silence the audible tone for two minutes.

Select **Help** for more information regarding alarm resolution.

If alarm conditions cannot be resolved, contact KCI.

Battery Low Alert

Low Priority Alert - This alert screen appears approximately two hours before the battery power level is too low to support continued operation of the V.A.C.Ulta™ Therapy Unit. This alert will be accompanied by a repeating audible tone.


Battery Low Alert
Battery low, charge required.
To charge battery, connect therapy unit to a power source using V.A.C. Ulta™ Power Cord, then press 'Reset'.
Symbol and light on front of unit will indicate charging status.
Audio Pause
Reset

To resolve this alert:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

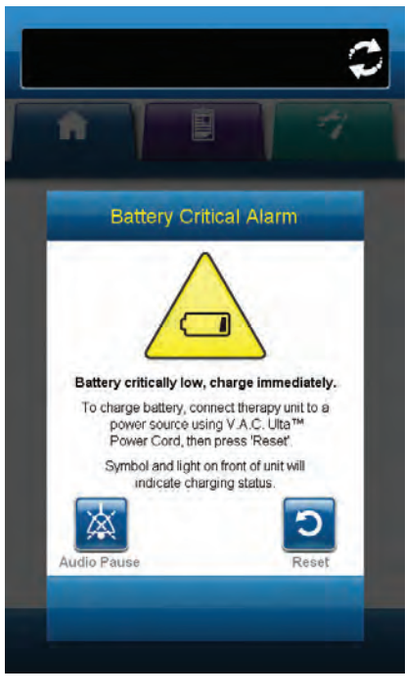
2. Connect the therapy unit to a wall outlet using the KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicate the unit is charging. Refer to the Charge Battery section of this manual (pg. 17) for more information.

3. Select **Reset** to return to the ***Home*** screen.

Therapy continues.

Battery Critical Alarm

Medium Priority Alarm - This alarm screen appears approximately 30 minutes before the battery power level is too low to support continued operation of the V.A.C.Ulta™ Therapy Unit. This alarm will be accompanied by a repeating audible tone.


Battery Critical Alarm
Battery critically low, charge immediately.
To charge battery, connect therapy unit to a power source using V.A.C. Ulta™ Power Cord, then press 'Reset'.
Symbol and light on front of unit will indicate charging status.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the Charge Battery section of this manual (pg. 17) for more information.

3. Select **Reset** to return to the ***Home*** screen.

4. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

V.A.C.® Therapy continues and V.A.C. VeraFlo™ Therapy transitions to V.A.C.® Therapy phase after approximately five minutes; however, if this alarm is not resolved within approximately 30 minutes, therapy will be interrupted.

Alarm logs and settings are not lost in the case of a total power loss or if the unit is power cycled (turned off then back on).

Canister Full Alarm (Therapy Interrupted)

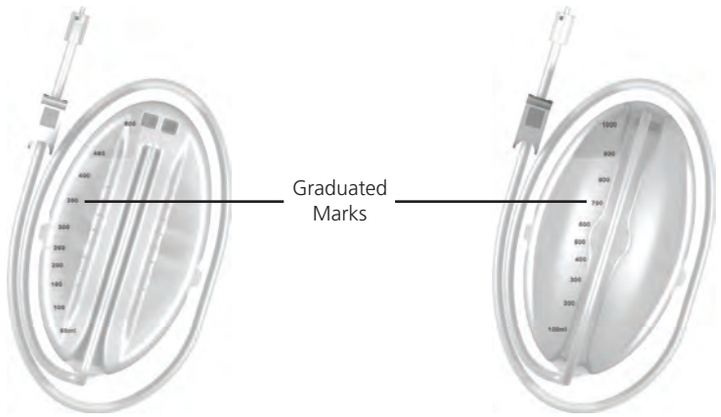
Medium Priority Alarm - This alarm screen appears when the canister is full and should be replaced. This alarm will be accompanied by a repeating audible tone.

Canister Full Alarm
Therapy Interrupted
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Check if canister is full by comparing the level of fluid to the graduated marks on the canister.



A full canister is approximately 300 mL, 500 mL or 1000 mL depending on canister used. Canister release button will be flashing.

3. If canister is not full, select **Reset** to return to the ***Home*** screen.

4. If canister is full, change canister and select **Reset** on this screen to return to the ***Home*** screen. See the Changing the Canister section of this manual (pg. 26) for additional information.

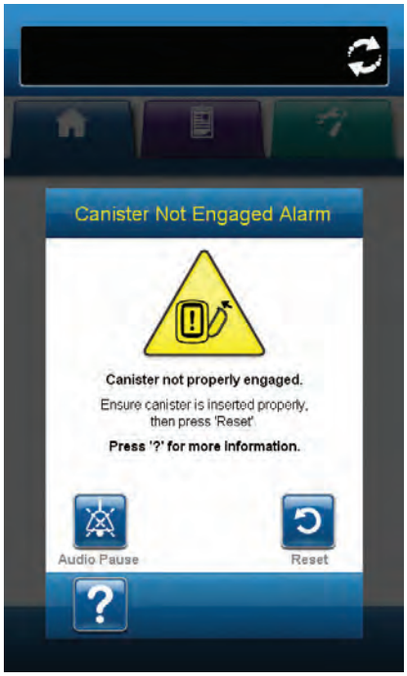
5. **V.A.C.® Therapy** - Select **Start / Stop** to restart therapy.

V.A.C. VeraFlo™ Therapy - Select **Pause / Resume** to restart therapy.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

Canister Not Engaged Alarm

Medium Priority Alarm - This alarm screen appears when the canister is not fully inserted and / or properly latched. This alarm will be accompanied by a repeating audible tone.


Canister Not Engaged Alarm
Canister not properly engaged.
Ensure canister is inserted properly, then press 'Reset'
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Remove the canister by pressing the **Canister Release** button (pg. 14) on the unit.

3. Inspect the canister and V.A.C.Ulta™ Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.

4. Ensure both seals are present and seated completely (pg. 15). If seals are missing or damaged, contact KCI.

5. Re-attach the canister to the V.A.C.Ulta™ Therapy Unit ensuring that the canister is fully engaged and latched (pg. 26). An audible click indicates that the canister is properly installed.

6. Select **Reset** to return to the ***Home*** screen.

7. **V.A.C.® Therapy** - Select **Start / Stop** to restart therapy.

V.A.C. VeraFlo™ Therapy - Select **Pause / Resume** to restart therapy.

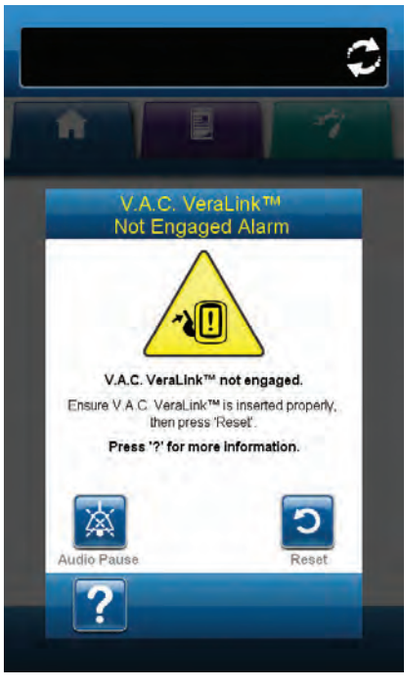
8. If this alarm continues to appear, repeat steps 1 - 7 with a new canister.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

V.A.C. VeraLink™ Not Engaged Alarm

Low Priority Alarm - This alarm screen appears when the V.A.C. VeraLink™ Cassette is not fully seated and / or properly latched. This alarm will be accompanied by a repeating audible tone.

During V.A.C. VeraFlo™ Therapy the V.A.C.Ulta™ Therapy Unit will transition to the Soak Phase upon initiation of this alarm and will continue to the V.A.C.® Therapy Phase before repeating the cycle. If V.A.C. VeraLink™ Cassette is correctly engaged prior to the completion of the V.A.C.® Therapy Phase, the V.A.C. VeraFlo™ Therapy cycle will not be interrupted.



To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
2. Remove the V.A.C. VeraLink™ Cassette from the unit by pushing down on the cassette latch release tab (pg. 22).
3. Inspect the V.A.C. VeraLink™ Cassette and the V.A.C.Ulta™ Therapy Unit to ensure no foreign objects or debris interfere with the cassette and the therapy unit connection points.
4. Ensure the cassette's pivot connection (on the end with the tubing spike) is securely engaged within the pivot slot on the therapy unit (pg. 15 and 22).
5. Re-attach the V.A.C. VeraLink™ Cassette to the therapy unit ensuring that the cassette is fully engaged and latched (pg. 22). An audible click indicates that the cassette is properly installed.
6. Select **Reset** to return to the ***Home*** screen.
7. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.
8. If this alarm condition continues to appear, repeat steps 1 - 7 with a new V.A.C. VeraLink™ Cassette.

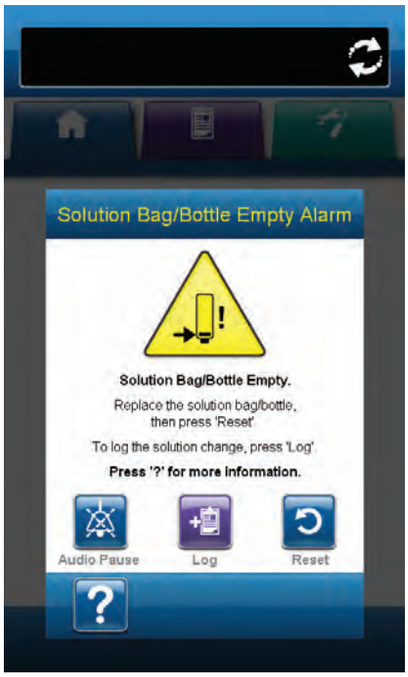
If alarm condition cannot be resolved, contact your healthcare provider or KCI.

If alarm condition occurs during the Instill phase of V.A.C. VeraFlo™ Therapy, the unit will transition to the Soak Phase.

Solution Bag/Bottle Empty Alarm

Low Priority Alarm -This alarm screen appears when there is no instillation fluid in the solution bag / bottle. This alarm will be accompanied by a repeating audible tone.

During V.A.C. VeraFlo™ Therapy the V.A.C.Ulta™ Therapy Unit will transition to the Soak Phase upon initiation of this alarm and will continue to the V.A.C.® Therapy Phase before repeating the cycle. If solution bag / bottle is changed prior to the completion of the V.A.C.® Therapy Phase, the V.A.C. VeraFlo™ Therapy cycle will not be interrupted.

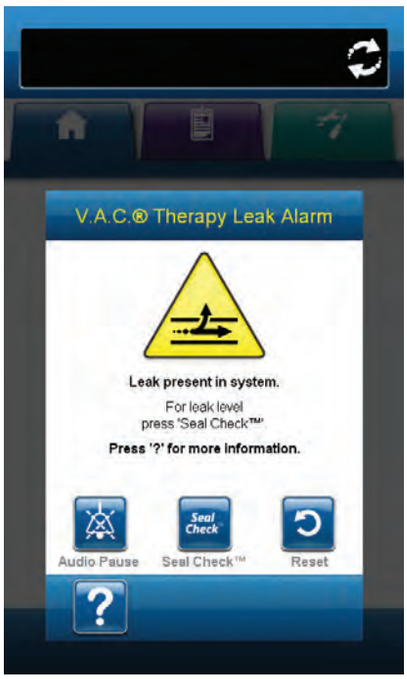


To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
2. Remove empty solution bag / bottle from V.A.C. VeraLink™ Cassette.
3. Attach new solution bag / bottle. Refer to Attaching Solution Bag / Bottle section of this manual (pg. 23) for more information.
4. Place new bag / bottle on the adjustable solution container hanger arm (pg. 23).
5. Select **Log** to enter the solution bag / bottle change. Refer to the ***Log*** screen section (pg. 55) for more information.
6. Select **Reset** to return to the ***Home*** screen.
7. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

V.A.C.® Therapy Leak Alarm

Medium Priority Alarm - This alarm screen appears when a significant negative pressure leak has been detected. If this alarm is not resolved in three minutes, therapy will be interrupted. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Ensure connector between dressing tubing and canister tubing is properly locked.

3. Ensure canister is fully engaged. (See Canister Not Engaged Alarm, pg. 89).

4. Select **Seal Check™** to access the Seal Check™ Leak Detector. Refer to the Seal Check™ Leak Detector section (pg. 53) of this manual for details on how to use the Seal Check™ Leak Detector and how to repair leaks.

5. Once the leak is resolved using the Seal Check™ Leak Detector, select **Exit** on the ***Seal Check™ Leak Detector*** screen to return to the ***V.A.C.®Therapy Leak Alarm*** screen.

6. Select **Reset** to return to the ***Home*** screen.

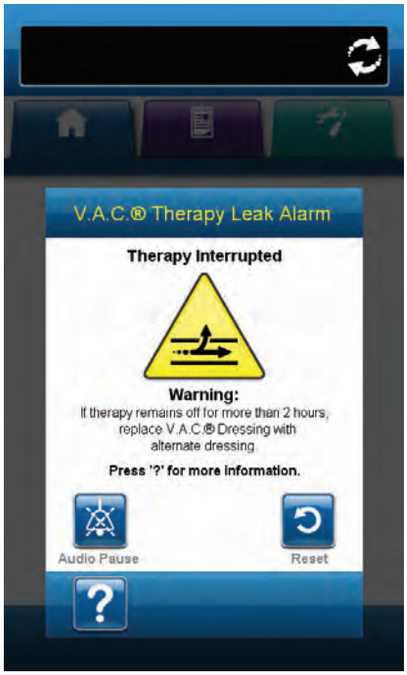
7. Ensure therapy is ON by checking the Status Bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

If this alarm is not resolved within three minutes, the V.A.C.® Therapy Leak Alarm (Therapy Interrupted) will appear and therapy will stop.

Refer to V.A.C.® Therapy Leak Alarm (Therapy Interrupted) section of this manual (pg. 93) for procedures to restart therapy.

V.A.C.® Therapy Leak Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a detected negative pressure leak has not been resolved and therapy has been interrupted. This alarm will be accompanied by a repeating audible tone.


V.A.C.® Therapy Leak Alarm
Therapy Interrupted
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Select **Reset** to return to the ***Home*** screen.

3. Restart therapy by selecting **Start / Stop**.

4. Select **Seal Check™** to access the Seal Check™ Leak Detector. Refer to the Seal Check™ Leak Detector section (pg. 53) of this manual for details on how to use the Seal Check™ Leak Detector and how to repair leaks.

5. Once the leak is resolved using the Seal Check™ Leak Detector, select **Exit** on the ***Seal Check™ Leak Detector*** screen to return to the ***Home*** screen.

If the leak condition is not resolved, this alarm screen will reappear after several minutes.

6. If the ***V.A.C.® Therapy Leak Alarm (Therapy Interrupted)*** screen reappears, select **Reset** again to return to the ***Home*** screen.

7. Repeat steps 1 - 5 as necessary until alarm is resolved.

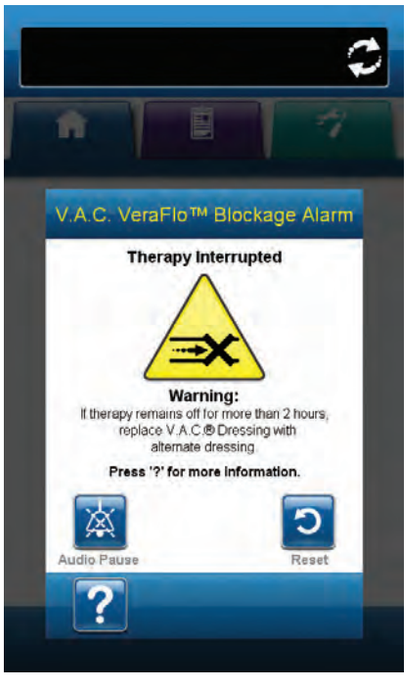
If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

V.A.C. VeraFlo™ Blockage Alarm (Therapy Interrupted)

Low Priority Alarm - This alarm screen appears when a blockage is present in the instillation line of the V.A.C. VeraT.R.A.C.™ Pad or V.A.C. VeraT.R.A.C. Duo™ Tube Set. This alarm will be accompanied by a repeating audible tone.

During V.A.C. VeraFlo™ Therapy the V.A.C.Ulta™ Therapy Unit will transition to the Soak Phase upon initiation of this alarm and will continue to the V.A.C.® Therapy Phase before repeating the cycle. If blockage is resolved prior to completion of the V.A.C.® Therapy Phase, the V.A.C. VeraFlo™ Therapy cycle will not be interrupted.


V.A.C. VeraFlo™ Blockage Alarm
Therapy Interrupted
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
2. Ensure clamps on the V.A.C. VeraT.R.A.C.™ Pad or V.A.C. VeraT.R.A.C. Duo™ Tube Set and V.A.C. VeraLink™ Cassette are open.
3. Ensure that the tubing is not kinked, crimped, or blocked in any way.
4. Ensure the V.A.C. VeraLink™ Cassette is fully engaged and latched. See the Attaching the V.A.C. VeraLink™ Cassette to the V.A.C.Ulta™ Therapy Unit section (pg. 22) of this manual for more information.
5. Ensure that the instillation solution in the V.A.C. VeraLink™ Cassette tubing is still liquid and flows freely. If the solution has degraded to a thicker consistency, change any or all of the following:
   - V.A.C. VeraLink™ Cassette
   - V.A.C. VeraT.R.A.C.™ Pad or V.A.C. VeraT.R.A.C. Duo™ Tube Set
   - Solution bag / bottle
6. If the V.A.C. VeraFlo™ Blockage Alarm remains after completing steps 1 - 5, check patient positioning or any external compression devices that may impede flow. If applicable, remove external compression device.

7. Select **Reset** to return to the ***Home*** screen.

8. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

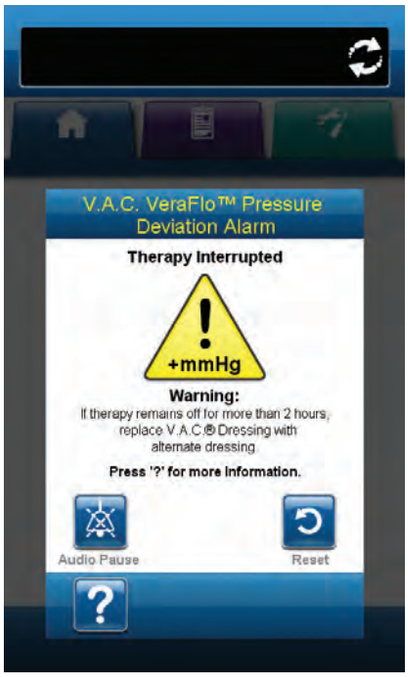
If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

V.A.C. VeraFlo™ Pressure Deviation Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the wound site positive pressure has exceeded its allowable limits. This alarm will be accompanied by a repeating audible tone.

During V.A.C. VeraFlo™ Therapy the V.A.C.Ulta™ Therapy Unit will transition to the Soak Phase upon initiation of this alarm and will continue to the V.A.C.® Phase before repeating the cycle. If pressure deviation condition is resolved prior to completion of the V.A.C.® Therapy Phase, the V.A.C. VeraFlo™ Therapy cycle will not be interrupted.


V.A.C. VeraFlo™ Pressure Deviation Alarm
Therapy Interrupted
+mmHg
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Ensure clamps on the V.A.C. VeraT.R.A.C.™ Pad or the V.A.C. VeraT.R.A.C. Duo™ Tube Set and V.A.C. VeraLink™ Cassette tubing are open.

3. Ensure that the tubing is not kinked, crimped or blocked in any way.

4. Ensure the V.A.C. VeraLink™ Cassette is fully engaged and latched. See the Attaching the V.A.C. VeraLink™ Cassette to the V.A.C.Ulta™ Therapy Unit section (pg. 22) of this manual for more information.

5. Ensure that the instillation solution in the V.A.C. VeraLink™ Cassette tubing is still liquid and flows freely. If the solution has degraded to a thicker consistency, change any or all of the following:

- V.A.C. VeraLink™ Cassette
- V.A.C. VeraT.R.A.C.™ Pad or V.A.C. VeraT.R.A.C. Duo™ Tube Set
- Solution bag / bottle

6. If the V.A.C. VeraFlo™ Pressure Deviation Alarm (Therapy Interrupted) remains after completing steps 1 through 5, check patient positioning or any external compression devices that may impede flow. Remove external compression device.

7. Select **Reset** to return to the ***Home*** screen.

8. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

Fill Assist Inactive Alarm

Low Priority Alarm - This alarm screen appears if the Fill Assist volume has not been accepted within 15 minutes of using Fill Assist. This alarm will be accompanied by a repeating audible tone

Fill Assist Inactive Alarm
'OK' button was not pressed on 'Fill Assist' screen.
'Fill Assist' volume was not recorded. Transitioning to V.A.C.® Therapy Phase.
To exit alarm, press 'Reset', then restart therapy.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Select **Reset** to return to the ***Home*** screen.

3. Select **Therapy Settings** on the ***Home*** screen (pg. 39).

4. Reconfigure therapy (pg. 35).

5. Verify that the **Fill Assist** slider is set to **ON** (default).

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

V.A.C.® Therapy Blockage Alert

Low Priority Alert - This alert screen appears when the V.A.C.Ulta™ Therapy Unit has detected a potential blockage. This alert will be accompanied by a repeating audible tone.

To resolve this alert:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VeraT.R.A.C.™ Pad, V.A.C. VeraT.R.A.C. Duo™ Tube Set or SensaT.R.A.C.™ Pad and canister tubing are open.

3. Ensure tubing is not kinked, crimped, or blocked in any way.

4. If the V.A.C.® Therapy Blockage Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

5. Select **Reset** to return to the ***Home*** screen.

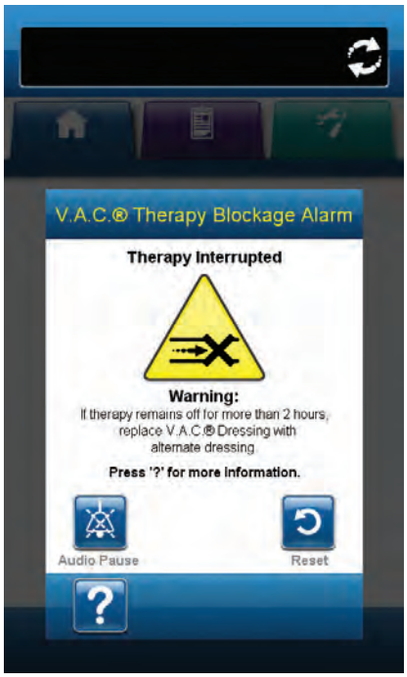
6. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

The V.A.C.Ulta™ Therapy Unit will continue to attempt to apply therapy during this alert.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

V.A.C.® Therapy Blockage Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a blockage is present. This alarm will be accompanied by a repeating audible tone.


V.A.C.® Therapy Blockage Alarm
Therapy Interrupted
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Press '?' for more information.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VeraT.R.A.C.™ Pad, V.A.C. VeraT.R.A.C. Duo™ Tube Set or SensaT.R.A.C.™ Pad and canister tubing are open.

3. Ensure tubing is not kinked, crimped, or blocked in any way.

4. If the V.A.C.® Therapy Blockage Alarm (Therapy Interrupted) remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.

5. Select **Reset** to return to the ***Home*** screen.

6. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

V.A.C.® Therapy Low Pressure Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the V.A.C.Ulta™ Therapy Unit has not reached the target therapy negative pressure setting and negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits. This alarm is accompanied by a repeating audible tone.

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VeraT.R.A.C.™ Pad, V.A.C. VeraT.R.A.C. Duo™ Tube Set or SensaT.R.A.C.™ Pad and canister tubing are open.

3. Ensure tubing is not kinked, crimped, or blocked in any way.

4. If the V.A.C.® Therapy Low Pressure Alarm (Therapy Interrupted) remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.

5. Select **Reset** to return to the ***Home Screen***.

6. Ensure therapy is ON by checking the status bar (pg. 39 or 45). If not, select **Start / Stop** to restart therapy.

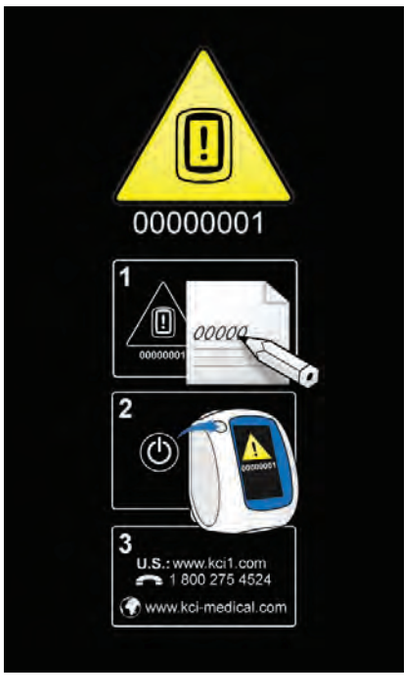
Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

System Error Alarm (at Power on)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.Ulta™ Therapy Unit while the unit is powering on. "00000001" represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:

1. Record the Error Code number (00000001).

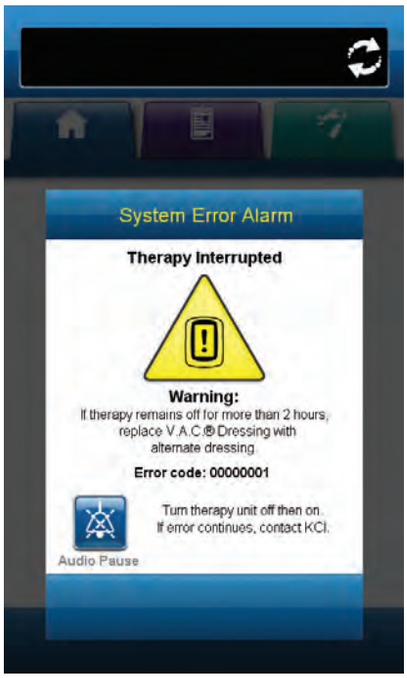
2. Power the unit off and then on using the **Power** button on the front of the unit (pg. 14).

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

System Error Alarm (Therapy Interrupted) (after Power on)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.Ulta™ Therapy Unit after it has been powered on. Several different types of system errors may occur. A number will appear next to Error Code: that represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.


System Error Alarm
Therapy Interrupted
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
Error code: 00000001
Turn therapy unit off then on. If error continues, contact KCI.
Audio Pause

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Record the Error Code number.

3. Power the unit off and then on using the **Power** button on the front of the unit (pg. 14).

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

Internal Temperature Alarm

Low Priority Alarm - This alarm screen appears when the internal temperature of the V.A.C.Ulta™ Therapy Unit has exceeded it specified limit. This alarm will be accompanied by a repeating audible tone.

Internal Temperature Alarm
°C
Internal temperature of therapy unit has exceeded specified limit.
Move therapy unit to an environment with operational temperature range specified in V.A.C. Ulta™ Therapy Unit user manual, then press 'Reset'.
Audio Pause
Reset

Therapy will continue while this alarm is active. The touch screen will be turned off after five minutes of inactivity. The screen will illuminate when touched. Battery charging is stopped.

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Move the therapy unit to an environment with an operational temperature range as detailed in the Specifications section of this manual.

3. Select **Reset** to return to the ***Home*** screen.

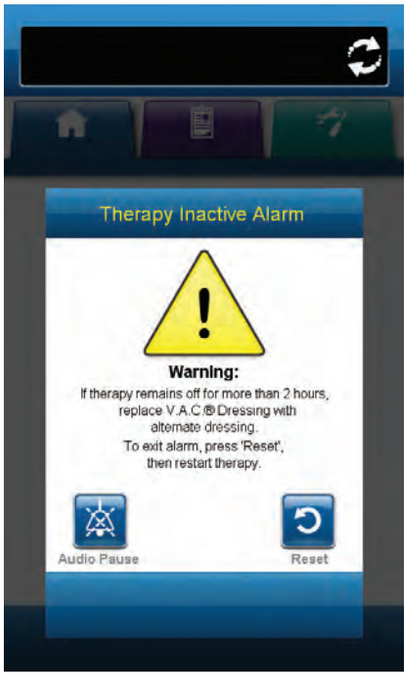
Therapy continues.

If alarm condition cannot be resolved, contact your healthcare provider or KCI.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

Therapy Inactive Alarm

Medium Priority Alarm - This alarm screen appears when therapy (V.A.C.® Therapy or V.A.C. VeraFlo™ Therapy) has been off or paused for more than 15 minutes (with the unit powered on) . This alarm will be accompanied by a repeating audible tone.


Therapy Inactive Alarm
Warning:
If therapy remains off for more than 2 hours, replace V.A.C.® Dressing with alternate dressing.
To exit alarm, press 'Reset', then restart therapy.
Audio Pause
Reset

To resolve this alarm:

1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.

2. Select **Reset** to return to the ***Home*** screen.

3. Select **Start / Stop** to restart therapy.

4. If therapy is not desired, turn the V.A.C.Ulta™ Therapy Unit off by using the **Power** button on the front of the unit.

Under clinician supervision, replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with an alternate dressing if therapy is interrupted for more than two hours.

Confirm Serial Number

This screen appears when the V.A.C.Ulta™ Therapy Unit is powered on and the serial number stored in the unit's memory is corrupt or missing.

Confirm Serial Number
Confirm or retype Serial Number located on therapy unit label.
Serial Number
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M
SPACE
DEL
OK

To resolve this alarm:

1. Compare serial number on unit's serial number label (pg. 14) to displayed serial number.

2. If serial number is incorrect, use the on-screen keyboard to re-enter the unit's serial number label.

3. Select **OK** to continue to the ***Startup*** screen.

Care and Cleaning

Standard Precautions

The following are the KCI recommended daily and weekly cleaning and infection control procedures for the V.A.C.Ulta™ Therapy Unit.

Always follow Standard Precautions.

Standard Precautions are designed to reduce the risk of transmission of microorganisms from both known and unknown sources of infection. These precautions can be applied to all patients, regardless of their diagnosis or presumed infection status, and should be used when contact is anticipated with blood and all body fluids. This also includes secretions and excretions (except sweat) regardless of whether blood is visible or not, non-intact skin (i.e., open wounds) and mucous membranes.

Waste Disposal

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations.

Cleaning the V.A.C.Ulta™ Therapy Unit

Cleaning and disinfection of the V.A.C.Ulta™ Therapy Unit includes wipe down of all hard surface components. Follow institutional procedures used for cleaning and disinfection of other hard surface durable electronic medical equipment. The V.A.C.Ulta™ Therapy Unit must be cleaned and disinfected:

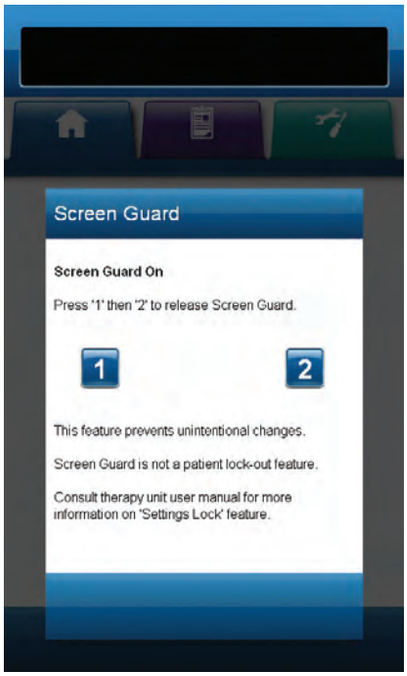
- If it becomes soiled during patient use.
- At least weekly.

Ensure that the V.A.C.Ulta™ Therapy Unit and its power supply are not connected to AC power when using cleaning fluids of any nature.

KCI recommends the following regarding cleaning and disinfecting KCI V.A.C.® Therapy devices:

- To help reduce risk of infection and contact with blood and body fluids, use personal protective equipment (PPE) such as medical procedure gloves.
- Clean all organic material (visible soil or body secretions) from the therapy unit prior to disinfection.
- Use hospital-grade cleaners and disinfectants.
- Do not immerse or saturate the therapy unit with fluids to avoid damage to the electronics in the device.
- Do not use alcohol based solutions around the touchscreen edges or near gasket and power switches since alcohol based solutions will easily wick up into the screen and may cause equipment malfunction.

Cleaning the Touch Screen


Screen Guard
Screen Guard On
Press '1' then '2' to release Screen Guard.
1
2
This feature prevents unintentional changes.
Screen Guard is not a patient lock-out feature.
Consult therapy unit user manual for more information on 'Settings Lock' feature.

1. Select **Lock** on the ***Home*** screen (pg. 39 or 45) to activate Screen Guard. The **Lock** icon will close.

2. Use a soft, non-abrasive cloth to gently clean the touch screen.

Do not use any liquid to clean the touch screen.

Do not use excessive force to clean the touch screen. Pressing too hard may cause damage.

3. To unlock the touch screen, touch the screen to display the ***Screen Guard*** screen.

4. Select the **1**, then the **2** on the ***Screen Guard*** screen to return to the ***Home*** screen.

Explanation of Symbols Used

Warning or Caution statement of possible hazard to system, patient or staff

Important Operational Information

Refer to Instruction Manual

IPX1

No protection against ingress of solid forcing objects. Protected against ingress of vertically dripping water.

Conforms with the Waste Electrical and Electronic Equipment Directive (2002/96/EC). At the end of useful life, dispose of all waste according to local requirements, or contact your local KCI subsidiary or agent for advice. This product is designated for separate collection at an appropriate collection point. Do not dispose of in normal waste stream.

Class II

Type BF Applied Part

Rx Only

CAUTION: Federal (US) law restricts this device to sale/rental by or on the order of a physician

Manufacturer

Authorized Representative in the European Community

Serial Number

Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

3182664

Control number issued by ETL based on manufacturing facility.

Specifications

Technical Specifications*

Classification

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

V.A.C.Ulta™ Therapy Unit

- Continuous Operation
- Type BF Applied Part
- Class II or internally powered equipment
- IPX1

Power Supply

- Class I Equipment
- Ordinary Equipment

V.A.C.Ulta™ Therapy Unit

Dimensions.....217mm X 260mm X 191mm (8.55in X 10.25in X 7.5in)

Weight.....3.35kg (7.4 lbs)

Electrical Data (Power Supply)

Voltage 100 - 240 VAC

Frequency 50Hz - 60Hz

Power 60W

Alarm Volume

Minimum of 72 dBA at 1 meter in maximum volume orientation.

* Specifications subject to change without notice.

Environmental Conditions

Transport and Storage Temperature Range..... -20 °C to +60 °C (-4°F to 140°F)

Operational Temperature Range.....+10 °C to +30 °C (50°F to 86°F)

Relative Humidity Range.....10% to 85% non-condensing

Barometric pressure Range.....700 hPa to 1060 hPa

Instill Pump Volumetric Accuracy

6 - 10 ml ± 2 ml

12 - 50 ml ± 20%

55 - 500 ml ± 15%

Accuracy Testing performed under the following conditions

Room Temperature: 22.5°C ± 2°C

Solution: 1000 mL bag of 0.9% saline fluid located on solution container hanger arm

Downstream pressure: 0 psi with discharge height at pump rotor centerline

Testing Duration: V.A.C. VeraLink™ Cassette usage up to 72 hours

Electromagnetic Compatibility

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 2004/108/EC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

The Essential Performance Requirements of the Model 60400 are to maintain 50 - 200 mmHg +/- 10 mmHg (60 second average) vacuum pressure with no false alarms.

Portable and mobile RF communications equipment can effect medical electrical equipment.

Radios, cell phones and similar devices may affect this equipment and should be kept at least 6.5 feet (2 meters) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the electromagnetic environment in which the V.A.C.Ulta™ Therapy Unit should be used in a clinical environment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The V.A.C.Ulta™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.Ulta™ Therapy Unit should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1 Class A	The V.A.C.Ulta™ Therapy Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Conducted emissions CISPR 11	Group 1 Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Yes	

Guidance and manufacturer's declaration - electromagnetic immunity			
The V.A.C.Ulta™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.Ulta™ Therapy Unit should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	In accordance with IEC 60601-1-2: 2007, floors are covered with synthetic material, the relative humidity should be at least (30)%.
Electrical fast transient / burst IEC 61000-4-4	±1kV Cables ±2kV Power	±1kV Cables ±2kV Power	
Surge IEC 61000-4-5	1kV line(s) to line(s) 2kV line(s) to earth	1kV line(s) to line(s) 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% half cycle 40% 5 cycles 70% 25 cycles 5% for 5 seconds	5% half cycle 40% 5 cycles 70% 25 cycles 5% for 5 seconds	
Power frequency (50Hz / 60Hz) magnetic field IEC 61000-4-8	3A/M	3A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_r is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the V.A.C.Ulta™ Therapy Unit			
The V.A.C.Ulta™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the V.A.C.Ulta™ Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V.A.C.Ulta™ Therapy Unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter meters**		
	150 kHz to 80 MHz **d =** $1.2\sqrt{P}$	**80 MHz to 800 MHz** **d =** $1.2\sqrt{P}$	**800 MHz to 2.5 GHz** **d =** $2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.37	0.74
1	1.2	1.2	2.3
10	3.8	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separate distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects and people.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The V.A.C.Ulta™ Therapy Unit is intended for use in an electromagnetic environment specified below. The customer or user of the V.A.C.Ulta™ Therapy Unit should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150K - 80 MHz 3V/meter 80 MHz - 2.5 GHz	3Vrms 150K - 80 MHz 3V/meter 80 MHz - 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the V.A.C.Ulta™ Therapy Unit, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended Separation Distance Battery Operated Device **d =** $1.2\sqrt{P}$ **d =** $1.2\sqrt{P}$ 80 MHz to 800 MHz **d =** $2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [1], should be less than the compliance level in each frequency range. [2] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the V.A.C.Ulta™ Therapy Unit is used exceeds the applicable RF compliance level above, the V.A.C.Ulta™ Therapy Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the V.A.C.Ulta™ Therapy Unit. [2] Over the frequency range 150kHz, field strengths should be less than 3V/m.			

Customer Contact Information

For questions regarding this product, supplies, maintenance, or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US call 1-800-275-4524 or visit www.kci1.com or www.vaculta.com

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350160 Rev B 1/2011